Request for Proposals: Implementation or Expansion of Nucleic Acid Testing for Diagnosis of Hepatitis C Virus Infection

Application Due date: December 14, 2022, 5PM ET

Submit to: Sarah Buss, Manager of HIV, Viral Hepatitis, STD and TB (sarah.buss@aphl.org) with a copy to Erin Estes, Specialist HIV, Viral Hepatitis, STD and TB (erin.estes@aphl.org)

The development of this request for proposals application was supported by Cooperative Agreement Number NU60OE000104 (CFDA #93.322) from the Centers for the Disease Control and Prevention (CDC) of the Department of Health and Human Services. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the CDC.
Table of Contents
Summary......................................................................................................................... 2
Background.................................................................................................................... 2
Eligibility .................................................................................................................... 3
Anticipated RFP Schedule.......................................................................................... 3
Response Submittal...................................................................................................... 4
Award ............................................................................................................................ 4
Term of Project........................................................................................................... 5
Evaluation Team ........................................................................................................ 5
Conflict of Interest ..................................................................................................... 5
Evaluation Criteria ..................................................................................................... 6
Evaluation Process ..................................................................................................... 6
Post-Evaluation Procedures ....................................................................................... 6
Conditions of Award Acceptance ............................................................................. 7
Proposal – Required Submissions .......................................................................... 7
Additional Information and Deadlines for Application Submission ....................... 8
Appendix A: Budget Guidance ............................................................................... 10
Appendix B: Scorecard .............................................................................................. 11
Appendix C: Conflict of Interest Disclosure Statement and Policy ......................... 16

Summary
The Association of Public Health Laboratories (APHL), in cooperation with the US Centers for Disease Control and Prevention (CDC) Division of Viral Hepatitis (DVH), is seeking to award one-time funding for up to twelve state or local public health laboratories (PHLs) for the purpose of establishing and/or enhancing capacity to implement the CDC recommended two-step HCV Diagnostic Testing Algorithm for the diagnosis of current HCV infection within a PHL. Funding will be awarded via a contract with APHL.

Background
APHL is a non-profit, 501(c)(3) organization that works to safeguard the public’s health by strengthening public health laboratories in the United States and globally. The Association’s members include state and local laboratories, state environmental and agricultural laboratories, and other government laboratories that conduct testing of public health significance. To obtain more information about APHL, please visit http://www.aphl.org.
Currently available HCV treatment regimens based on direct antiviral agents (DAA) have been shown to achieve cure in >90% HCV infected individuals. Diagnosis remains the first step in these treat-to-cure HCV infection regimens. In 2013, the CDC emphasized the importance of identifying cases of current HCV infections in order to promptly link to care and prevent further transmission, and provided diagnostic testing recommendations in “Testing for HCV Infections: an Update of Guidance for Clinicians and Laboratorians.” These recommendations begin with an FDA-approved HCV antibody test which if reactive should be followed with an FDA-approved nucleic acid test (NAT) to detect HCV RNA. If HCV RNA is detected the person is considered to have current HCV infection and should be linked to care for clinical evaluation and treatment.

This testing algorithm has been recommended since 2013, but a 2022 survey of US public health laboratories (PHLs) indicated that while 92% of PHLs performing HCV testing offered a laboratory based HCV antibody immunoassay, only 48% of those performed an HCV RNA NAT for diagnosis of HCV infection, and only 34% reflexed HCV antibody positive samples to an in-house HCV NAT. To help address this gap in HCV RNA testing APHL established an HCV NAT Reference Center in 2018. The reference center is meant to serve PHLs with a limited volume of samples requiring HCV NAT. PHLs with a higher volume of HCV antibody reactive specimens need to make alternative arrangements for HCV RNA testing.

There continues to be a steady rise in the number of acute hepatitis C cases in the US based on the most recent 2019 surveillance data. These rises have been partially attributed to both the increased surveillance and the ongoing and increasing injection drug use related to the opioid crisis. To address the rising rates of hepatitis C cases and the need for complete diagnostic testing to link persons with current infection to treatment, APHL with CDC-DVH is excited to announce this one-time funding opportunity. The aim of this funding opportunity is to assist PHLs with any aspect of implementation or expansion of HCV RNA testing in order for PHLs to complete the two-step HCV testing algorithm inhouse without having to refer to another laboratory nor require an additional visit/blood-draw.

**Eligibility**

All state or local US public health laboratories are eligible to apply for the one-time funding, though priority will be given to public health laboratories who were not awarded a contract for expansion of HCV NAT in 2020.

**Anticipated RFP Schedule**

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>November 2, 2022</td>
<td>RFP Issued</td>
</tr>
</tbody>
</table>
| **November 23, 2022** | **Required Letter of Intent Due to APHL (see below) *NOTE:**  
|                     | This deadline has been extended from the original date  
|                     | (November 16)                               |
| December 14, 2022   | RFP Responses Due                          |
| December 23, 2022   | Proposal review completed                  |
| January 2-9, 2023   | If needed, follow-up interviews and updated proposals due |
January 16, 2023 Final review completed and awardees selected
February 1, 2023 Estimated contract start date

APHL will communicate any modification to this anticipated schedule on APHL’s procurement website (www.aphl.org/rfp) and via an email blast to the public health laboratories.

Response Submittal

Confirmation of Intent to Respond
To allow for appropriate review process planning, a letter of intent is required for consideration. APHL requires that prospective applicants submit a brief email statement indicating an intent to submit a proposal to sarah.buss@aphl.org with a copy to erin.estes@aphl.org. APHL must receive this email by no later than 5:00pm EST on November 23, 2022.

Final Response
APHL must receive complete responses by 5:00 pm EST on December 14, 2022. Please see ProposalRequired Submissions section for items that must be included in the completed proposal. Applicants may send proposals via email to sarah.buss@aphl.org with a copy to erin.estes@aphl.org.

APHL will send an email acknowledging the receipt of your application; if you do not receive an acknowledgement within 48 hours, please email the RFP point of contact above to confirm receipt.

Award
Funding will be distributed via a contract administered by APHL. Up to twelve laboratories, depending on strength of applications, funding requested, and funds available, will be selected. Award amounts will depend on the scope of the proposed project with an estimated award per site of $10,000-$25,000.

Use of funds: Funds may be used for activities contributing to implementation or expansion of laboratory capacity for HCV RNA testing or implementation of automatic reflexing of HCV Ab reactive specimens directly to HCV RNA but may not be used to contract with an outside facility to provide testing services. The activities listed below (singularly or in any combination) are examples of expenditures appropriate for the scope of the RFP. You may also propose other activities aimed at improving diagnosis of current HCV infection and enabling completion of the recommended HCV testing algorithms. While not preferred, funds could be used for establishing internal procedures or processes for automated reflexing to another laboratory if sufficient justification could be provided for how this will improve testing capacity for your jurisdiction.

1. Purchasing reagents or supplies for validation/verification of:
   a. a new HCV RNA for diagnostic purposes
   b. a new sample type(s) or stability condition that would enable reflexing of HCV antibody positive samples directly to an HCV NAT
c. automation for HCV RNA testing
2. Procuring samples for validation/verification of an HCV RNA assay if not available elsewhere
3. Modification of current testing workflows to enable more efficient HCV RNA testing and reporting (i.e., aliquoting samples on receipt or otherwise setting up automatic reflexing of HCV antibody reactive samples directly to HCV RNA testing)
4. Update existing laboratory information management systems (LIMS) for any of the following activities: electronic ordering and reporting of laboratory results, instrument interfaced ordering and reporting, and/or for implementation of automated reflexing of HCV antibody reactive samples to HCV NAT
5. Implementation of third-party billing to foster sustainability
6. Working to provide outreach to clinical laboratories and/or physicians on ordering practices and collection of appropriate clinical specimens to enable automatic reflex testing of HCV antibody positive samples

Term of Project
From date of contract signing (approximately February 1, 2023) through June 30, 2023. Please note that all proposed projects should be feasible to complete by that date. A final progress report will be required as a final deliverable. We do anticipate funding projects with a small, feasible scope. Up to 50% of the proposed amount will be made available at the start of the project and 50% upon completion.

Evaluation Team
APHL staff, led by the HIV, Viral Hepatitis, STD and TB (HHST) Program Manager, will conduct an initial review of all proposals for completeness. Any application that is incomplete as of the proposal due date specified in the Anticipated RFP Schedule section above will not be considered and will not receive a formal evaluation.

Complete proposals will be reviewed by a team of three subject matter experts (SMEs) from CDC’s Division of Viral Hepatitis and a panel of three APHL members selected from non-applicant public health laboratories. SMEs from CDC will be identified and selected by the Chief of the Laboratory Branch of the Division of Viral Hepatitis based on their familiarity with project requirements. APHL member experts will be identified from among the non-applicant laboratories by the APHL HHST Program Manager and will have expertise in the laboratory testing methods described in this RFP. Once potential reviewers have been identified, APHL’s Director of Infectious Disease Programs will have final approval over the review team’s composition.

Conflict of Interest
APHL will ask potential reviewers to complete and sign APHL’s Conflict of Interest Disclosure Statement to disclose any real or perceived conflict of interest prior to the start of the evaluation process. Reviewers will have to affirm that they have no conflict of interest that would preclude an unbiased and
objective review of the proposals received. A copy of the disclosure statement and the related Fiduciary Responsibility and Conflict of Interest Policy is attached as Appendix C: Conflict of Interest Disclosure Statement and Policy. APHL will not select reviewers with a perceived or potential conflict of interest. This Conflict of Interest Disclosure Statement is provided in the RFP for Applicant review only. Applicants should not complete the Conflict of Interest Disclosure Statement unless instructed by APHL.

Evaluation Criteria
The evaluation team will evaluate proposals based on responses to the questions in the Proposal – Required Submissions section and will give a numeric score of up to 100 maximum points based on the scorecard template in Appendix B.

Evaluation Process
The evaluation team will conduct the review via a combination of email communication between APHL’s HHST Program Manager and the members of the evaluation team, or among the evaluation team members and teleconference and/or webinar evaluation sessions. APHL’s HHST Program Manager will coordinate the review process and the evaluation sessions.

The reviewers may request follow-up interviews with all or some of the applicant laboratories and, following these interviews, may request supplemental information on an applicant’s proposal. The evaluation team will use these interviews and any supplemental information to clarify a laboratory’s capacity or experience in one or more of the evaluation criteria, or to explain other information contained in an applicant’s proposal.

There will be no formal evaluation performed by a member of APHL staff. In cases where all other evaluation criteria are substantially similar, APHL will have the ability to advise the evaluation team on selections that would provide geographical spread or otherwise diversify APHL’s funding allocations. In addition, the evaluation team may receive documentation from APHL staff on an applicant’s past performance in other capacities as part of the evaluation criteria.

Post-Evaluation Procedures
APHL staff will notify the selected laboratories within ten business days of the completion of the evaluation and will post the names of the recipient(s) to APHL’s procurement website, www.aphl.org/rfp, within three (3) business days of the laboratory’s acceptance of the award. Unsuccessful applicants will receive notification of these results by e-mail within 30 days after the name of the selected awardee is posted.

All applicant laboratories will be entitled to utilize APHL’s RFP Appeals Process to formulate a protest regarding alleged irregularities or improprieties during the procurement process. Specific details of this policy are located on the procurement website.
Conditions of Award Acceptance
The eligible laboratory must be able to contract directly with APHL or have an existing relationship with a third-party organization that can contract directly with APHL on behalf of the laboratory*.
Laboratories must agree to comply with budgetary expectations outlined in Appendix A. Acceptance of the award means agreement to the compensation structure and amounts agreed upon with the awardee and APHL.
* Laboratories must be legally able to contract within the United States and not disbarred or prohibited from contracting with businesses or the federal government.

Proposal – Required Submissions
An interested laboratory must submit both a letter of intent to apply (due November 23, 2022) and a proposal (due December 14, 2022). Applications must comply with submission requirements set out in the Additional Information and Deadlines for Application Submission below. A complete proposal will include the following items:

Responses to Questions (below)

- Responses should be limited to no more than six (6) single spaced pages (font size > 11pt, > 1inch margins) including one (1) page for the budget.
- The proposal should include responses to the questions below, including each aspect of the question. For Question 4, only answer the relevant subparts. The proposal should clearly indicate what question is being answered.

Response to Proposal Questions

Please review and respond to every question in your proposal. Note that for Question 4, only the subparts relevant to your proposed work need to be addressed.

1. **Current Testing Capability**: Describe the laboratory’s existing HCV testing capabilities (HCV Antibody and HCV RNA) to include specimen types accepted and received, test(s) performed, testing algorithm, how often testing is performed, turnaround time, annual volume, and billing practices.

2. **Current Staffing**: Describe the qualifications and experience of existing laboratory staff trained to perform HCV testing including familiarity with validation/implementation of new test methods.

3. **Project Description**: Provide a description of how your laboratory intends to use the one-time funding to establish or improve existing HCV RNA testing capabilities or automatic reflexing
capabilities. Ensure you provide a brief explanation (3-5 sentences) of why these one-time funds are needed. Depending on your approach please address the relevant sub-parts of this question.

a. **If Applicable:** Provide the proposed updated testing algorithm for HCV testing once all new methods are implemented.

b. **If Applicable:** Provide details related to the specimen types that will be accepted (serum, plasma, etc.), workflow, specimen management (i.e., will same specimen be used for HCV antibody and HCV RNA testing or will two specimens be required), and discuss how you will ensure specimen integrity for molecular testing.

c. **If Applicable:** Describe any relevant staff training that will be required to implement and/or expand testing capacity.

4. **Detailed Description of Approach:** Please also address the relevant sub-parts of this question to provide more detailed information on your plans.

a. **If Applicable:** Please describe your validation/verification plans, including the estimated timeline for implementation of the assay. Please ensure you are accounting for the time needed for validation plans, report approvals, LIMS modifications etc.

b. **If Applicable:** Please describe using basic terms your plans for LIMS modifications related to ordering and reporting, to include the timeline for testing and implementation.

c. **If Applicable:** Please describe currently available equipment/testing platforms that will be leveraged and/or if new equipment is required, please describe your ability to procure such equipment in a timely manner.

d. **If Applicable:** Please describe your plans for communicating any changes to your HCV testing and/or providing ongoing education to submitters and stakeholders (including your jurisdictional hepatitis program).

5. **Measuring Success:** Please describe at least one, and up to three, specific and measurable objectives that allow for assessment of impact and sustainability of the project.

6. **Sustainability:** Please provide a brief description of how these one-time funds will be leveraged to generate sustainable HCV RNA testing capacity in your laboratory and be sure to address how testing will be funded in the future.

7. **Budget:** Provide a line-item budget reflecting the requested funding amount. Please refer to Appendix A for more details. For each category of funding requested (supplies, travel, training materials, etc.), include a brief description of how the requested items support the proposed activities. Please limit your response to no more than one (1) single-spaced page.

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**Additional Information and Deadlines for Application Submission**

Applicants must direct all questions to Sarah Buss at (sarah.buss@aphl.org). APHL will post questions received from interested PHLs, together with the answers provided by APHL or CDC staff to APHL’s procurement website associated with the specific RFP (www.aphl.org/rfp). APHL will try to post responses on a rolling basis, within 1 business day of receipt of the question.
To allow for appropriate review process planning, a letter of intent is required for consideration. Applicants should submit letters by email to Sarah Buss at APHL (sarah.buss@aphl.org) with a copy to Erin Estes (erin.estes@aphl.org) no later than 5:00 pm ET on Wednesday November 23, 2022. Applications are due Sarah Buss at APHL (sarah.buss@aphl.org) with a copy to Erin Estes (erin.estes@aphl.org) by 5:00 pm ET on Wednesday December 14, 2022. APHL will send an email acknowledging the receipt of your application. If you do not receive an acknowledgement within two (2) business days, call 240-485-3901 to confirm receipt.
Appendix A: Budget Guidance

Budgets should be prepared to reflect costs through June 30, 2023. Budgets should be divided into the line items shown below. A guideline for each line item is described for preparation of the budget and justifications. It is not appropriate to include staff time on this one-time funding award.

Supplies/Reagents

Provide a total supply budget and list each item included in that budget. Listing the cost of individual items is helpful and appreciated. Provide justification for each item and describe how it will be used to validate/implement or expand HCV NAT testing. General laboratory or safety supplies not specifically used for NAT testing, such as gloves, pipettes, lab coats, etc., are not appropriate for this award.

Equipment/Instrumentation

Equipment/Instrumentation should be listed in priority order, with the first item being of highest priority. Provide justification for the use of each item and describe how the item will be used to validate/implement or expand HCV NAT capacity. Maintenance costs for equipment should be shown in the Other category.

* Given the size of each award, it is unlikely we will be able to cover the total cost of a piece of equipment. However, we are open to payment for a portion of equipment, offsetting costs associated with leasing equipment and/or service agreements.

* If durable equipment that costs > $5,000 is purchased using these funds, the cost must be reported to APHL as part of our cooperative agreement reporting.

Other

This category contains items not included in the previous budget categories. Appropriate items for inclusion include, but are not limited to, relevant IT expenses, maintenance contracts, shipping expenses for validation isolates and training costs. Individually list each item and the amount requested and provide appropriate justification for how the item will be used to validate/implement or expand HCV NAT methods.

Additional Costs Budget (optional)

Laboratories may include an additional costs budget reflecting additional funds needed (above the anticipated amount of this award) to fully validate/implement or expand HCV NAT methods in their laboratory and or jurisdiction, to meet jurisdictional needs. This budget should also include a brief description of how the funds would be used and should be prepared using the instructions found above. * This information will assist APHL and DVH in determining the allocation of additional funds if they become available.
Appendix B: Scorecard
The following table is a copy of the score card that will be used to evaluate RFP responses.

<table>
<thead>
<tr>
<th>Category/Question</th>
<th>Maximum Value</th>
<th>Score</th>
<th>Comments (REQUIRED)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Does the applicant provide a sufficient description of their plans including a general approach clear explanation and justification for why these funds are needed to establish or improve HCV RNA testing capacity in their jurisdiction? (Question 3)</td>
<td>20</td>
<td></td>
<td></td>
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**Applicant expresses significant and appropriate need:** Jurisdiction has not implemented HCV RNA, needs to expand specimen acceptance criteria for reflexing requirements and/or may struggle to reflex HCV antibody reactive samples to HCV RNA without additional support (14-20 points).

**Applicant expresses appropriate and moderate need:** Jurisdiction has implemented HCV RNA but demonstrates how funds would improve current HCV RNA testing and/or implement/improve reflexing of HCV antibody reactive samples to HCV RNA (6-13 points).

**Applicant expresses minimal need:** Jurisdiction has an HCV RNA method in place and can already autoreflex HCV antibody reactive samples to HCV RNA test but has reasonable request to utilize funds (1-5 points). **Insufficient information to assess need** (0 points).
2. Does the applicant provide sufficient detail to describe their approach to implement their plan to validate/verify or otherwise expand HCV RNA testing and/or automatic reflexing of HCV antibody reactive specimens to an HCV RNA test and communicate their changes to relevant stakeholders? (Question 4)

| No issues or concerns: Sufficient information and appropriate approach (20 points). | 20 |
| Minor concerns: Some information missing to fully assess and/or some minor concerns with approach (14-19 points). |
| Moderate concerns: Information missing to fully assess plan and/or moderate concerns with the approach (6-13 points). |
| Major concerns: Significant information missing to fully assess plan and/or major concerns with the approach (1-5 points). |
| Insufficient information to assess plan and/or inappropriate approach (0 points) |
3. Considering the proposed approach (Questions 3 and 4) -- does the applicant have the appropriate current testing capabilities (Question 1) and appropriate staffing (Question 2) and/or mechanisms to obtain additional assistance?

*Consider the following:* Does the applicant have appropriate equipment and space, and/or the ability to obtain additional equipment (4c) and supplies to perform new testing method? Does the applicant provide a timeline for implementation of the new method that aligns with the project period (Question 3 and 4)?

| No issues or concerns: Applicant has or will build capacity and capability to execute their proposed plans within established timelines (20 points). |
| Minor concerns: There are minor concerns about the applicant’s capacity and capability to execute the proposal within the proposed timeline (13-19 points). |
| Moderate concerns: There is missing information and/or there are moderate concerns about the applicant’s capacity and capability to execute the proposal within the proposed timeline (6-12 points). |
| Major concerns: There are major concerns about the applicant’s capacity and capability to execute the proposal within the proposed timeline (1-5 points). Applicant will not be able to implement plans based on the information provided (0 points). |
| 4. Does the applicant provide at least one and up to three specific, measurable objective(s) that will enable them to assess the impact of the funding (Question 5)? |
|---|---|
| **No concerns with stated objective(s):** Objective(s) are appropriate, clear, specific and measurable (15 points). | 15 |
| **Minor to moderate concerns with objective(s):** Objective(s) may not be totally appropriate, clear, specific or measurable but are generally acceptable to measure impact (8-14 points). | |
| **Major concerns:** Objective(s) are not entirely appropriate, clear, specific or measurable and would be difficult to use for measuring success/impact (1-7 points). | |
| **Objective(s) not provided and/or don’t address impact** (0 points). | |

<table>
<thead>
<tr>
<th>5. Does the applicant address how the funds will be used to create a sustainable HCV RNA testing program given the one-time nature of these funds (Question 6)?</th>
<th>15</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>No issues or concerns:</strong> Applicant clearly defines how testing program will be sustained in the future (15 points).</td>
<td></td>
</tr>
<tr>
<td><strong>Minor to moderate concerns</strong> about the applicant’s ability to create a sustainable testing program within the jurisdiction (8-14 points).</td>
<td></td>
</tr>
<tr>
<td><strong>Major concerns</strong> about the applicant’s ability to create a sustainable testing program or insufficient information provided to assess sustainability (1-7 points).</td>
<td></td>
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<tr>
<td><strong>Funding will not create a sustainable testing program and/or no information provided</strong> (0 points).</td>
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</table>
6. Does the applicant provide an appropriate budget for the requested funding? (Question 7)

- **No concerns with budget** (10 points).
- **Minor to moderate concerns with budget** (5-9 points).
- **Major Concerns with budget** (1-4 points).
- **Budget not appropriate for proposal** (0 points).

<table>
<thead>
<tr>
<th>TOTAL SCORE</th>
<th>100</th>
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Appendix C: Conflict of Interest Disclosure Statement and Policy
(APPLICANTS NEED NOT COMPLETE UNLESS INSTRUCTED BY APHL)

Association of Public Health Laboratories
Conflict of Interest Disclosure Statement

Applicability: Disclosure of the following information is required of all Officers, Directors, committee members, staff members and other volunteers who have been designated and who have accepted responsibility to act on behalf of APHL (“APHL Personnel”). Please answer the following questions and, where indicated, include the same information for your immediate family members (your parents, your spouse or partner, your children and your spouse/partner’s parents). APHL will keep your completed disclosure statement in the corporate records of the association.

1. Please list the name, address, phone number, email address and type of business of your current employer. If you are self-employed, please note that below and provide us with the address, phone number, email address and type of business you operate.

__________________________________________________________________________

__________________________________________________________________________

__________________________________________________________________________

2. Do you, or does any family member, currently serve as an officer, director, committee member, or other volunteer (or work as an employee of or a paid consultant to) any organization serving the interest of laboratory science or public health laboratories other than APHL or your state or local laboratory?

☐ Yes ☐ No

If yes, please list the organization(s) and provide detail on your or your family member’s interest or position in the organization(s).

__________________________________________________________________________

__________________________________________________________________________

__________________________________________________________________________
3. Do you, or any family member, have an existing or potential interest in, or compensation arrangement with, any third-party providing goods or services to APHL, or with which APHL is currently negotiating? ☐ Yes ☐ No
If the answer is yes, please provide the name of the organization below and describe in detail the nature of the position held.

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

4. Please note any other financial or business interest you may have with any organization serving the interests of public health laboratories.
If you have none, please check this box: ☐

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

5. Do you, or does any family member, have any other interest or affiliation that is likely to compromise your ability to provide unbiased and undivided loyalty to APHL, or that could come in conflict with your official duties as an Officer, Director, committee member, staff member or other volunteer who has been designated and who has accepted responsibility to act on behalf of APHL? ☐ Yes ☐ No
If you answered yes, please describe in detail below the nature of each such interest or affiliation.

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

6. If you are currently aware of any actual or possible conflict of interest that might otherwise hamper your ability to serve APHL to your best ability and with the highest degree of care, loyalty and
obedience – including any potential conflict you or a family member may have with one or more of the RFP applicants – please describe them in detail below.


7. Do you agree that so long as you are an Officer, Director, committee member, staff member or other volunteer who has been designated and who has accepted responsibility to act on behalf of APHL you will immediately disclose to the other Directors and/or Officers or, for staff members, the Executive Director and/or General Counsel the nature of any interest or affiliation which you may hereafter acquire, which is in or is likely to become in conflict with your official duties with APHL? ☐ Yes ☐ No

YOU MUST READ THIS SECTION AND THEN SIGN BELOW

I acknowledge that I have received and read APHL’s Fiduciary Responsibility and Conflict of Interest Policy (the Policy). I have listed all my relevant fiduciary responsibilities and affiliations, and I have identified any actual or potential conflict of interest on this Disclosure Statement, and I agree to abide by the Policy. I understand that it is my responsibility to inform APHL in writing of any change in circumstances relating to the Policy and this Disclosure Statement.

Signature: ___________________________ Date: ________________

Printed Name: ___________________________

APHL Fiduciary Responsibility and Conflict of Interest Policy

1. Policy Statement and Purpose

The members of the APHL Board of Directors understand the importance of serving APHL to the best of their ability and with the highest degree of obedience, loyalty and care. Accordingly, the Board adopts the following policy for APHL Officers and Directors, all staff, committee members, and other volunteers who have been designated and who have accepted responsibility to act on behalf of APHL (“APHL Personnel”).
2. Individual Duty and Annual Disclosure

APHL Personnel will avoid any conflict of interest with APHL. APHL Personnel will not profit personally from their affiliation with APHL, or favor the interests of themselves, relatives, friends or other affiliated organizations over the interests of APHL. As used in this Policy, "Conflict of interest" includes any actual, apparent, and potential conflict of interest.

Upon commencing service with APHL, each APHL Personnel will file with the Board an annual statement disclosing all material business, financial, and organizational interests and affiliations they or persons close to them have which could be construed as related to the interests of APHL or the profession of public health laboratory science. Each APHL Personnel has an obligation to make an additional disclosure if a conflict of interest arises in the course of the individual's service to APHL, whether arising out of his/her employment, consulting, investments, or any other activity. These disclosures will be documented promptly in writing and recorded in the Board minutes and corporate records.

3. Procedure

Whenever APHL considers a matter, which presents an actual, apparent, or potential conflict of interest for APHL Personnel, the interested individual will fully disclose his/her interest in the matter, including the nature, type, and extent of the transaction or situation and the interest of the individual or that individual's relatives, friends or other affiliated organizations. The Board, after consultation with counsel as appropriate, will determine whether an actual and material conflict exists and, if so, what is the appropriate course of action under this policy and the Board vote will be recorded in the minutes.

Any Board member having a conflict of interest must either (i) voluntarily abstain from and be disqualified from participation in all deliberation and voting on all Board actions relating to the situation or matter that gives rise to the conflict of interest, or (ii) ask the Board to determine whether an apparent or potential conflict of interest is considered by the Board to be an actual and material conflict. In the event that the Board member in question requests that the Board evaluate the apparent or potential conflict, that Board member will abstain and be disqualified from participating in (and voting on) the determination of whether the issue presents an actual and material conflict. If the Board determines that an actual and material conflict exists, the Board member in question will abstain from all voting on, and will be disqualified from participation in all deliberation concerning all Board actions relating to the conflict of interest. The vote will be recorded in the minutes.

These procedures will neither prevent the interested individual from briefly stating his/her position on the matter, nor preclude him/her from answering pertinent questions of Board members, since his/her knowledge may be of assistance to the Board’s deliberations.

APHL Personnel must be cautious and protective of the assets of APHL and insure that they are used in the pursuit of the mission of APHL. The association’s policy requires APHL Personnel to avoid transactions in which APHL personnel may have a significant financial interest in any property which
APHL purchases, or a direct or indirect interest in a supplier, contractor, consultant, or other entity with which APHL does business. The Board, after consultation with counsel as appropriate, will determine whether an actual and material conflict exists and, if so, determine whether the transaction is nonetheless favorable to APHL before considering whether to approve it.

4. Other Duties and Obligations

Whenever any APHL Personnel discovers an opportunity for business advantage which is relevant to the activities of APHL, the opportunity belongs to APHL and the individual must present this opportunity to the Board. Only once the Board determines not to pursue the matter and relinquishes the opportunity may the individual consider it a matter of possible personal benefit.

APHL Personnel may not accept favors or gifts exceeding $75.00 from anyone who does business with APHL.

All APHL Personnel will keep confidential those APHL matters designated confidential. APHL Personnel are prohibited from disclosing information about APHL to those who do not have a need to know or whose interest may be adverse to APHL, either inside or outside APHL, and are prohibited from using in any way such information for personal advantage to the detriment of APHL.

All APHL Personnel who participate in APHL activities, including committee activities and international consultation activities, must be adequately prepared to fully participate as their position descriptions require and will do so in accordance with the applicable laws and regulations of their respective state or territory and APHL’s Articles of Incorporation, Bylaws, and corporate policies. The APHL Board will read and understand the association’s Articles of Incorporation, Bylaws, corporate policies and financial statements, and routinely verify that all state, federal, and local tax payments, registrations and reports have been filed in a timely and accurate manner.

Board members will never exercise authority on behalf of APHL except when acting in meetings with the full Board or the Executive Committee or as authorized by the Board. If any member of the Board has significant doubts about a course of action of the Board, he or she must clearly raise the concern with the Executive Director and the Board and, when appropriate, seek independent expert advice.