Request for Proposals: Influenza Sequencing Center

Application Due date: **December 12**, 2022

Submit to: Melissa Warren, Senior Specialist, Influenza (melissa.warren@aphl.org)

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Summary

The Association of Public Health Laboratories (APHL), in cooperation with the US Centers for Disease Control and Prevention's (CDC) Influenza Division (ID), is seeking to identify up to five (5) state or local public health laboratories (PHLs) to serve as Influenza Sequencing Centers (ISCs) in support of national influenza surveillance initiatives. The sequencing centers will perform influenza virus genomic sequencing on specimens fromt their jurisdictions using next generation sequencing (NGS) based methods and a data assembly pipeline approved by APHL and CDC.

Background

State and local public health laboratories are the foundation of the US influenza surveillance system. PHLs collect and test specimens, reporting this information to the CDC. This information is included in national surveillance data to describe which viruses are circulating and at what prevalence. Furthermore, PHLs play a critical role in the vaccine strain selection process by providing specimens to CDC for further antigenic and genetic characterization. Data from PHLs and the viruses submitted to CDC are compiled and shared with the international community to help determine vaccine compositions for future seasons. These same viruses help CDC detect and monitor variant viruses and antiviral resistant viruses.

Influenza virus genomics is central to understanding evolution of emerging lineages important in prevention (e.g., vaccine updates) and response (e.g., antiviral drugs). APHL and CDC have supported three (3) National Influenza Reference Centers (NIRCs) for a wide range of analysis (e.g., genomic sequencing, virus isolation, and antiviral analysis.) Influenza virus genomics has enabled the detection of evolutionary mechanisms central to viral fitness and immune escape, antiviral resistance mutations, reassortment and other genomic changes within a single data set. High throughput genomics is facilitating timely intervention strategies and improved data availability for vaccine strain selection.

The ISCs will serve as a valuable source of timely genomic surveillance data in US locations that are geographically diverse and/or transit hubs. Additionally, they will increase the overall national capacity for processing specimens for vaccine strain selection and detecting antiviral resistant viruses.

Eligibility

Eligible laboratories include all US public health laboratories with the following capabilities, resources and facilities in place. Specific expectations regarding the methodologies to be used by the reference center are outlined in Appendix A: *Expectations for Influenza Sequencing Center*. All applicants are required to agree to the following minimum requirements (as outlined in Appendix B: Minimum Requirements for Influenza Sequencing Center):

1. Surveillance networks are in place to receive specimens required to sequence 500 specimens per year;
2. Sufficient equipment, laboratory space and workforce capacity for the proposed work;
3. Established capacity to perform influenza NGS while meeting expected quality metrics;
4. Willingness to alter or amend existing sequencing protocols;

Submit the Letter of Intent (Due 12/02/2022) and completed application (Due 12/12/2022) to Melissa Warren, melissa.warren@aphl.org

5. Willingness to increase frequency of performing certain methods (if required) to meet expected turnaround times;
6. Ability to collect all required metadata;
7. Willingness to share copies of QA or biosafety documentation associated with relevant procedures to APHL and CDC upon request;
8. Informatics capabilities to stream NGS read-level data to APHL Informatics Messaging Services (AIMS) cloud-based environment in near real-time using the Amazon Simple Storage Service (S3) Utility synchronization tools with IT support;
9. Ability to upload consensus genomic data to public database with prescribed naming convention and required metadata;
10. Ability to retain residual clinical specimens (properly stored, not inactivated) for up to 12 months post-selection for sequencing and provide CDC with specimens, upon request, for additional characterization/use at CDC;
11. Ability to contract with APHL have an existing relationship with a third party that can contract directly with APHL on behalf of the laboratory.

Anticipated RFP Schedule

November 11, 2022	–	RFP Issued
November 29, 2022	–	Informational teleconference (optional)
December 2, 2022	**–**	**Letter of Intent Due to APHL (see below)**
December 12, 2022	–	**RFP Responses Due**
January 6, 2023	–	Proposal review completed
January 11, 2022	–	As needed, follow-up interviews/proposals due
January 12, 2022	–	Final review completed and awardees selected
January - June 2023	–	Contract year one (training and proficiency testing)

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

Response Submittal

Confirmation of Intent to Respond

APHL requires that prospective applicants submit a brief email statement indicating an intent to submit a proposal. APHL must receive this email by no later than **5:00 pm EST on Friday, December 2, 2022. To allow for appropriate review process planning, a letter of intent is required for consideration.**

Final Response

APHL must receive complete responses by **5:00 pm EST on Monday, December 12, 2022**. Please see Proposal-Required Submissions section for items that must be included in the completed proposal. Applicants may send proposals via email to melissa.warren@aphl.org.

APHL will send an email acknowledging the receipt of your application; if you do not receive an acknowledgement within 2 business days, please email the RFP point of contact above to confirm receipt.

Award

APHL and CDC will select up to five laboratories to perform this work. The amount of each award may vary year to year based on testing performed and volume of specimens available. Funding is available for ISCs to sequencing up to 500 specimens per year. Funding is distributed through an annual contract with APHL. By accepting the award, laboratories agree to these rates for a three-year time span barring substantive changes in scope or material expenses at APHL's discretion.

Compensation will be $150 per specimen per sequence attempted. Repeat runs that are required due to laboratory or human error are not reimbersible.

Use of funds: Recipient laboratories should use the funding for sequencing (including retesting due to laboratory/personnel error), reagents and consumables and personnel time required to conduct these activities and may be used for necessary equipment upgrades or expansions, equipment maintenance and service agreements or validation of new testing services.

Term of Project

The project term will be from January 2023 through June 30, 2023. Additional activities may precede this start term if needed to establish testing capacity, data transmissions and proficiency demonstrations to ensure operational expectations are in place for seasonal surveillance.

The potential for annual renewals (with each additional funding year running from July 1 to June 30) by APHL is based on availability of funds and performance of the awardee for a maximum of two additional years (to end June 30, 2025). Each of the potential renewals may involve some adjustment to the scope of work in order to address any change in the funding received by APHL and to accommodate CDC programmatic needs in that funding year. The awardees will be notified in advance of any modification to the anticipated scope of work in a future funding year.

Evaluation Team

APHL staff, led by the Influenza Senior Specialist, will conduct an initial review of all proposals for completeness. Any incomplete application on the proposal due date specified in Anticipated RFP Schedule section above will not be considered and will not receive a formal evaluation.

A team of three subject matter experts (SMEs) from the CDC Influenza Division (ID) and a panel of three APHL members selected from non-applicant public health laboratories will review complete proposals. The ID Virology, Surveillance, and Diagnosis Branch (VSDB) Chief will identify and select SMEs from the CDC, based on their familiarity with laboratory techniques and project requirements. The APHL Respiratory Disease Manager will identify APHL member experts from among the non-applicant laboratories. These members will have expertise in the laboratory testing methods described in this RFP and familiarity with APHL sequencing center structure. APHL's Director of Infectious Disease Programs has 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** in order 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 D**: 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 C.

Evaluation Process

The evaluation team will conduct the review via a combination of email communication between APHL's Influenza Senior Specialist and the members of the evaluation team, or among the evaluation team members and teleconference and/or webinar evaluation sessions. APHL's Influenza Senior Specialist 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 representation 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 expectations outlined in Appendix A. Acceptance of the award means agreement to the compensation structure and amounts agreed upon with the awardee and APHL.

Prior to making the official award, a group of individuals from CDC and APHL will be entitled to elect to tour the facilities to assess compliance with requirements for testing and/or have a teleconference with applicant laboratories. Post award, monitoring site visits may be conducted to include an assessment of continued compliance.

Proposal – Required Submissions

An interested laboratory must submit both a letter of intent to apply (due December 2, 2022) and a proposal (due December 12, 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:

- **A completed and signed copy of Appendix B,**

  Note: If your laboratory cannot respond "yes" to each of the minimum requirements, your laboratory does not meet the minimum qualifications required to apply for this award.

- **A letter of support from your institution's IT department:**
  a. Confirming your commitment to maintain connectivity to the AIMS S3 Utility/SDK environment with the support of a designated IT staff member **OR**

  b. Confirming your ability to establish connectivity to the AIMS S3 Utility/SDK environment with the support of a designated IT staff member

- **Responses to Questions (below)**
    - Responses should be limited to no more than ten (10) single spaced pages (font size ≥ 11pt, 1 inch margins)
    - The proposal should include responses to the questions below, including each aspect of the question. The proposal should indicate what question is being answered.

Response to Questions

Physical Environment

1. Briefly, describe the physical space (e.g. room set up, what testing services spaces are shared with, equipment and location, unidirectional flow) that would be used for all work including:
    a. Specimen receipt
    b. Extraction
    c. Amplification
    d. Library Preparation
    e. Sequencing
    f. Post run analysis
2. Does your laboratory use a core facility for sequencing? If so, please describe the core's resources, what other groups they are serving and how influenza sequencing center work would be prioritized.
    a. Include information on how the ISC staff work and coordinate with the core staff and at which step the specimen hand off occurs.

Workforce

1. Does your laboratory have staff with the subject matter expertise to implement influenza sequencing and post-run analysis?
    a. Please describe the qualifications and experience staff have in providing, producing and analyzing sequence data, including uploading final data to the National Center for Biotechnology Information (NCBI) or other public database.
    b. List any applicable trainings staff have received.

NGS Methods

2. Please describe the current NGS methodologies (metagenomics, pull down, amplicon based, etc.) used in your laboratory. Include information on:

a. how long the each methodology has been in use;
b. What pathogens have you been performing for each methodology;
c. how often NGS is performed;
d. volume of complete genomes in the past year including the type (pathogen) of genomes that were sequenced;
e. quality metrics including pass/fail rate, minimum depth of coverage, and modification and retraction of submissions;
f. usage of controls including evaluation of controls, how they are monitored over time, etc.;
g. average turnaround time; and
h. average run size and total capacity.

3. Are you able to accommodate weekly-dedicated influenza runs?
4. How does your laboratory troubleshoot sequencing issues and failed runs?

Laboratory Informatics and Bioinformatics

5. Describe your sample management process and integration with sequencing, if implemented. Please describe your Laboratory Informatics Management System's (LIMS) ability to integrate sequencing data, if applicable.
6. Are you willing/able to use Clarity LIMS for NGS workflow management?
    a. If you have previous experience with Clarity LIMS, please describe.
    b. If you are not a current Clarity LIMS user, do you have plans to purchase Clarity LIMS in the next 12 months.
7. Describe your process for sequence assembly and post-run analysis.
8. Describe your post-assembly data curation process. Additionally, include any public databases to which your laboratory uploads sequence data.
9. Describe your ability to transmit sequence data to cloud-based storage. Do you currently have a connection to AIMS/Amazon Web Services (AWS) S3?

Geographical Location and Submitter Network

10. Describe your jurisdiction's influenza surveillance system, including the populations and networks from which you recieve specimens and your proposed approach for obtaining approximately 85 specimens per month during influenza season (approximately October-March). Specimens should be geographically, demographically and clinicaly diverse.

Additional Information and Deadlines for Application Submission

Applicants must direct all questions to Melissa Warren (melissa.warren@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).

To allow for appropriate review process planning, a **letter of intent is required for consideration**. Applicants should submit letters by email to Melissa Warren at APHL (melissa.warren@aphl.org) no later than **5:00 pm EST on December 2, 2022.**

Applications are due to Melissa Warren at APHL (melissa.warren@aphl.org) **by close of business (5:00pm ET) December 12, 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 240-485-2741 to confirm receipt.

APHL will hold an optional teleconference on November 29, 2022 at 2:00pm ET. The purpose of this call will be to provide a brief overview of the project and to allow potential applicants to ask CDC and APHL questions. Please come with questions prepared.

Teleconference Call-in Information is below, or please contact melissa.warren@aphl.org or infectious.diseases@aphl.org no later than 3:00pm ET on November 28, 2022 to receive the calendar invitation.

Join Zoom Meeting:
https://aphl.zoom.us/j/84267424945?pwd=TlVCODlRUzdja295NjMrNDZYRFVWdz09

One tap mobile
+13017158592,,84267424945#,,,,*830901# US

Meeting ID: 842 6742 4945
Passcode: 830901

Appendix A: Expectations for Influenza Sequencing Centers

Methods and Test Algorithms

Molecular biological approaches needed

- RNA extraction and purification, influenza genome enrichment as described by CDC (e.g., Multisegment RT-PCR) NGS library preparation and NGS is expected to be run on a weekly basis during the influenza season.
    - Runs will be dedicated to influenza specimens. Laboratories should not add additional pathogens to the influenza run.
    - Runs may be postponed by one week if the run is less than 20 viruses to conserve reagents.
- The laboratory will use the Illumina platform or Oxford Nanopore technologies (ONT) for NGS.
- The laboratory must successfully complete a limit of detection panel and performance evaluation panel of reference viruses prior to starting testing on surveillance specimens.

Data Curation and Analysis

- The sequencing center will utilize Clarity LIMS and pre-configured Tableau Online dashboards for workflow management and sequence data analysis for each run.
- The laboratory will perform data curation and bioinformatics analysis utilizing the AIMS workspace and protocols provided by CDC.

Data Transmission

- Laboratory Information Management System in place and able to export desired specimen level data to Clarity LIMS or alternative solution through a manual or scripted process.
- The capacity and capability to transmit data through APHL Informatics Messaging Services platform (AIMS) S3 bucket.
- The ability to upload consensus genomic data to a designated CDC or public database.

Performance Management and Evaluation

Next Generation Sequencing

Laboratories will perform a limit of detection panel and a proficiency panel annually, at a minimum. Once active surveillance testing starts, the sequencing center must submit monthly reports, including number of specimens tested and turnaround time, to APHL and CDC. The laboratory is responsible for complying with all pre-determined quality checks at key stopping points within the laboratory workflow and quality checks within the curation workflow of assembled sequence data to minimize reagent waste and troubleshooting effort. Potential quality issues should be escalated immediately to CDC for review.

Site visits and teleconferences

Submit the Letter of Intent (Due 12/02/2022) and completed application (Due 12/12/2022) to Melissa Warren, melissa.warren@aphl.org

- As needed, CDC and APHL will conduct a site visit for training new laboratories with CDC's protocols and to ensure surveillance testing is ready to start. Additional monitoring visits may be needed based on data review and any ongoing challenges mutually identified. Site visits could include data review, review of laboratory workflow, procedural observation, QC information and review of worksheets and database.
- APHL in collaboration with CDC will host a mandatory monthly teleconference for the sequencing centers to provide status updates and discuss any ongoing challenges and potential solutions.

Project Evolution

- Successful laboratories will need to have flexibility to meet the project requirements as national surveillance needs evolve over time. Any deviations in the scope of work, including updates to CDC standard operating procedures (SOPs), will be reviewed on an annual basis and after a training period. Laboratories will adopt all changes within a mutually agreed implementation period.

Storage and submission to CDC

- Upon CDC request, specimens may be shipped to CDC for additional characterization and/or workup as a potential vaccine candidate virus.
- Specimens will be stored frozen by the ISC for a period of 1 year.

Appendix B: Minimum Requirements for Influenza Sequencing Center

Please review and respond to each of the minimum requirements below. By signing this agreement you are affirming that your laboratory can meet each of the minimum requirements described.

YES	NO	MINIMUM REQUIREMENT
		Does your laboratory have the surveillance networks in place to receive specimens required to sequence 500 specimens per year?
		Does your laboratory have sufficient equipment, laboratory space and workforce capacity for the proposed work?
		Does your laboratory have established capacity for next generation sequencing while meeting quality metrics?
		Is your laboratory willing to alter or amend existing sequencing protocols?
		Is your laboratory willing to increase the frequency of performing certain methods (if required) to meet expected turnaround times?
		Does your lab have the ability to collect all required metadata?
		Is your laboratory willing to provide copies of QA or biosafety documentation to APHL and CDC upon request?
		Does your laboratory have informatics capabilities to stream NGS read-level data to APHL Informatics Messaging Services (AIMS) cloud-based environment in near real-time using the Amazon Simple Storage Service (S3) Utility synchronization tools with IT support?
		Does your laboratory have the ability to upload consensus genomic data to public database with prescribed naming convention and required metadata?
		Does your laboratory have the ability to retain residual clinical specimens (properly stored, not inactivated) for up to 1 year post-selection for sequencing and provide CDC with specimens, upon request, for additional characterization/use at CDC?
		Is your laboratory able to contract with APHL or do you have an existing relationship with a third party that can contract directly with APHL on behalf of the laboratory?

On behalf of the applicant laboratory, I agree that the applicant laboratory is able to meet the minimum requirements necessary to apply for this award as outlined above.

Signature: _____ Date: _____

Printed Name: _____

Submit the Letter of Intent (Due 12/02/2022) and completed application (Due 12/12/2022) to Melissa Warren, melissa.warren@aphl.org

Appendix C: Score Card

The following table is a copy of the score card that will be used to evaluate RFP responses.

Category/Question	Maximum Value	Score	Comments (REQUIRED)
Physical Environment 1. Does the applicant have appropriate physical space and workflow to handle the proposed sequencing volume? Consider the availability of existing equipment and space and the ability of the laboratory to purchase additional equipment. 2. If the application uses a core facility, do they demonstrate the ability to coordinate and prioritize the proposed work to ensure dedicated influenza sequencing runs with the desired turnaround time? **Ideal** (7-10 points): Describes ability to handle testing volume for all activities; describes appropriate equipment and space or ability to obtain additional equipment in a timely manner. **Adequate** (4-6 points): Describes ability to meet most testing volume requirements but may have to adjust workflow to accommodate work; has some deficiencies in their equipment or ability to obtain additional resources. **Limited** (1-3 points): Applicant describes limited ability to meet testing volume requirements; has many deficiencies in their equipment or ability to obtain additional resources. **Inadequate** (0 points): Applicant does not demonstrate the ability to handle the testing volume for all methods and neither has the current equipment or ability to obtain the unmet needs and/or does not demonstrate a clear understanding of the requirements.	10		Type comments here. (REQUIRED)
Workforce 3. Does the applicant describe in-house staffing and subject matter expertise that is sufficient to implement influenza sequencing and post-run analysis? Consider experience in providing, producing and analyzing sequence data, including uploading final data to NCBI or other public databases. **High** (7-10 points): Applicant has a enough staffing and strong history of relevant experience, subject matter expertise: at least 1.0 FTE with > 5 years or 2.0 FTEs with > 3 years of experience performing NGS. **Moderate** (4-6-points): Applicant has staffing and some relevant experience but will require additional training, guidance or technical assistance in others, subject matter expertise: >1.0 FTE with ≥ 3 years of experience performing NGS.	10		Type comments here. (REQUIRED)

Low (1-3 points): Deficiencies in staffing in this area, subject matter expertise: ≤ 1 FTE with <3 years of experience performing NGS **No Experience** (0 points): Applicant does not demonstrate internal subject matter expertise is this area.			
NGS Methods 4. Does the applicant have sufficient capacity and experience performing NGS? Consider experience with Illumina/Oxford Nanopore. 5. Is the applicant able to accommodate weekly dedicated influenza runs? 6. Does the applicant have adequate quality assurance processes and troubleshooting plans in place? **High** (18-25 points): Describes extensive experience utilizing Illumina platform on relevant pathogens with good depth of coverage, pass/fail rate and rare submission recalls, sufficient capacity and staff experience to handle additional volume, describes appropriate staffing and equipment, and regularly meets target turnaround times. **Moderate** (11- 17 points): Describes sufficient experience performing method with adequate depth of coverage, pass/fail rate and limited submission recalls, some concerns about appropriate capacity to handle additional volume and/or does not demonstsrate ability to regularly meet target turnaround times. **Low** (3-10 points): Describes experience performing method with limited depth of coverage, unsatisfactory pass/fail rate and moderate number of submission recalls deficiencies in workforce experience and/or ability to meet target turnaround times and/or handle additional volume. **No /Unclear** (0-2 points): Applicant does not demonstrate or has limited ability to conduct NGS.	25		Type comments here. (REQUIRED)
Informatics/Bioinformatics 7. Does the applicant have experience using Clarity LIMS or are they willing to use it? 8. Does the applicant have sufficient demonstrated experience performing sequence assembly, post-run analysis including data curation and transmission to public databases? **High** (15-20 points): Describes extensive experience to perform sequencing assembly, post-run analysis, data curation and data transmission. **Moderate** (10-14 points): Describes sufficient experience or limitations in one area to perform sequencing assembly, post-run analysis, data curation and data transmission.	20		Type comments here. (REQUIRED)

Low (5-9 points): Describes limited experience in more than one area performing method, to perform sequencing assembly, post-run analysis, data curation and data transmission. **No /Unclear** (0-4 points): Applicant does not demonstrate ability to perform sequence analysis.			
Data Transmission 9. What is the applicant's ability to transmit sequence data? **Ideal** (10 points): Applicant already has a connection to AIMS/AWS S3 **Adequate** (5 points): Applicant has the ability to connect to AIMS/AWS S3 **Inadequate** (0 points): Applicant does not have an electronic test orders and results (ETOR) system or ability to connect to AIMS/AWS S3	10		Type comments here. (REQUIRED)
Georgraphical Location and Influenza Network 10. Does the applicant's jurisdiction's influenza surveillance system include specimens from geographic, demographic and clinically diverse populations and networks. Will the applicant be able to obtain approximately 85 specimens per month during influenza season (approximately October-March). **Ideal** (18-25): major international transit hub and/or major metropolitan area within the applicant's jurisdiction; applicant has surveillance network established and will be able to receive 85 samples per month **Adequate** (11-17): minor international transit hub and/or minor metropolitan area within the applicant's jurisdiction; applicant has surveillance network established and will be able to receive less than 85 samples per month **Limited** (3-10): minor international transit hub and/or minor metropolitan area within the applicant's jurisdiction; applicant has a limited surveillance network established and is not able to recieve 85 samples per month **Inadequate** (0-2): jurisdiction does not contain a transit hub or large population) or does not have a robust surveillance network	25		Type comments here. (REQUIRED)
TOTAL SCORE	**100**	____	

Appendix D: Conflict of Interest Disclosure Statement and Policy

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.