



Request for Proposals: Validation of the MALDI-TOF for the Identification of *Neisseria gonorrhoeae*

Application Due date: August 16, 2017

Submit to: Anne Gaynor, Manager of HIV, viral Hepatitis, STD and TB
(Anne.Gaynor@aphl.org)

Summary

The Association of Public Health Laboratories (APHL), in cooperation with the US Centers for Disease Control and Prevention's (CDC) Division of STD Prevention (DSTDP) is seeking to enlist up to five state or local public health laboratories to assist with the validation of a MALDI-TOF for the identification of *N. gonorrhoeae*. Selected laboratories will participate in a working group charged to design and collect a robust panel of *N. gonorrhoeae* and other commensal *Neisseria* species from various anatomic sites to be used in an identification challenge panel. The laboratories will test the constructed panels to assess the utility of a MALDI-TOF identification system.

Background

N. gonorrhoeae is one of the most common sexually transmitted infections (STIs) with approximately 100 million cases worldwide and is the second most common notifiable communicable infection in the United States with more than 300,000 cases being reported annually to the CDC. Increasing global tourism and migration complicates infection control strategies that attempt to limit spread through early detection and effective treatment. The treatment of gonorrhea is increasingly difficult as multi-drug resistant strains have been identified throughout the world, but the frequency of those resistant to current CDC and WHO recommended therapies remain low. A thorough understanding of molecular epidemiological and transmission dynamics is urgently needed to identify sexual networks and risk factors associated with emerging resistant strains. The detection of antimicrobial resistant *N. gonorrhoeae* requires viable isolate and the application of standard bacteriologic susceptibility tests developed over 40 years ago. In contrast, most gonococcal infections are detected using nucleic acid amplification tests that can be used with a variety of specimen types and are not limited by strict transport conditions required to maintain viability. CDC recommends that specimens be tested using

nucleic acid amplification tests and that labs maintain culture capacity to assess *N. gonorrhoeae* isolates recovered from patients that presumably failed therapy. Applying technologic advances to bridging simple detection with antimicrobial susceptibility has lagged due to the array of genetic mechanisms associated with resistant *N. gonorrhoeae* and ongoing emergence of new mutations. It's therefore critical that traditional microbiologic approaches to assessing antimicrobial susceptibility remain as the mainstay for detecting emerging drug resistance.

In the last decade, the MALDI-TOF has become increasingly used for the identification of clinically important bacteria and fungi. The test takes minutes to perform and can shorten the time for identification by avoiding metabolic and/or enzymatic tests. Though some studies have reported on the utility of the MALDI-TOF for the identification of *N. gonorrhoeae* there has been little attempt to standardize a validation panel that could be used by laboratories with an interest in using the test for clinical reporting. This funding mechanism would provide an opportunity for the development and assessment of a *N. gonorrhoeae* MALDI-TOF validation panel for use by state or local public health laboratories. Please note this is a one-time funding opportunity.

Eligibility

Eligible laboratories include all member public health laboratories with the following capabilities and facilities in place. Specific expectations regarding methodologies to be used by the awardees are outlined in [Appendix A](#): Expectations for the MALDI-TOF Validation of *N. gonorrhoeae*. All applicants are required to agree to the following minimum requirements (as outlined in [Appendix B](#));

- 1) Unrestricted access to a MALDI-TOF instrument (Bruker or bioMérieux Vitek);
- 2) Demonstrated competency and capacity using MALDI-TOF to perform bacterial identification;
- 3) Demonstrated competency and capacity for bacterial culture including *Neisseria* species but not limited to *N. gonorrhoeae*; and
- 4) Sufficient equipment, laboratory space and workforce capacity for the proposed work.

Anticipated RFP Schedule

July 7, 2017	–	RFP Issued
July 31, 2017	–	Letter of Intent Due to APHL (see below)
August 16, 2017	–	RFP Responses Due
August 30, 2017	–	Proposal review completed
September 8, 2017	–	If needed, follow-up interviews and updated proposals due
September 11, 2017	–	Final review completed and awardees selected
September 30, 2017	–	Draft contracts submitted to APHL Legal Dept. for final internal review

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

Please send the Letter of Intent (Due 7/31/17) and completed application (Due 8/16/17) to Anne Gaynor, anne.gaynor@aphl.org

Response Submittal

Confirmation of Intent to Respond

APHL requests that prospective applicants submit a brief email statement indicating an intent to submit a proposal. APHL must receive this email by no later than **5:00pm EST on July 31, 2017**.

Final Response

APHL must receive complete responses by **5:00 pm EST on August 16 2017**. Please see [Proposal-Required Submissions](#) section for items that must be included in the completed proposal. Applicants may send proposals by the following methods:

Via email to Anne.Gaynor@aphl.org or

Via Mail (USPS, FedEX, UPS) addressed to:
Association of Public Health Laboratories
Attn: ANNE GAYNOR
8515 Georgia Avenue, Suite 700
Silver Spring, MD 20910

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 points of contact above to confirm receipt.

Award

Up to five laboratories, depending on the strength of applications, will be selected. Each selected site will be eligible for an award of up to \$5,000 which will be distributed via a contract administered with APHL.

Term of Project

The project term will be from the date of notification through June 30, 2018 and the expected contract term will cover the period from October 1, 2017 through June 30, 2018. APHL anticipates that from the date of notification to the start date of the contract the selected site will work with APHL and CDC on work group calls to define the sample set, review the proposal and ensure mechanisms are in place for specimen and data transfer from the CDC to the laboratory. The potential for annual renewals (with each additional funding year running from July 1 to June 30) may be considered by APHL based on availability of funds and performance of the awardee for a maximum of two additional years. 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 awardee would be notified in advance of any modification to the anticipated scope of work in a future funding year.

Please send the Letter of Intent (Due 7/31/17) and completed application (Due 8/16/17) to Anne Gaynor, anne.gaynor@aphl.org

Evaluation Team

APHL staff, led by the HHST Program Manager, 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.

Complete proposals will be reviewed by a team of three subject matter experts (SMEs) from CDC DSTDP and a panel of three APHL members selected from non-applicant public health laboratories. SMEs from CDC will be identified and selected by the DSTDP SMEs based on their familiarity with laboratory techniques and project requirements. APHL member experts will be identified from among the non-applicant PHLs by the APHL HHST Program Manager and will have expertise in the laboratory testing methods described in this RFP and familiarity with APHL reference center structure.

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 and 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.

Once potential reviewers have been identified, APHL's Director of Infectious Disease Programs will have final approval over the review team's composition.

Evaluation Criteria

Proposals will be evaluated based on the responses to the questions in the [Proposal – Required Submissions](#) section and will receive a numeric score of up to 100 maximum points based on the scorecard template in [Appendix C](#).

Laboratories will also be given preference based on more extensive experience with the test methods, ability to handle increased test volume for *Neisseria gonorrhoeae*, , ability to comply with expectations laid out in [Appendix A](#) and the ability to meet the minimum expectations outlined in [Appendix B](#).

Evaluation Process

The entire review will be conducted 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. These interviews and any supplemental information would 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.

Please send the Letter of Intent (Due 7/31/17) and completed application (Due 8/16/17) to Anne Gaynor, anne.gaynor@aphl.org

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 noted in this RFP as part of the evaluation criteria.

Post-Evaluation Procedures

The selected laboratories will be notified by APHL staff within ten business days of the completion of the evaluation and the names of the recipient will be posted to APHL's procurement website, www.aphl.org/rfp on the same day. Unsuccessful applicants will receive notification of these results by e-mail or by U.S. mail within 30 days of the date the name of the winning vendor 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](#).

The eligible laboratory must be able to receive specimens and report results to all submitting partners in the proposal.

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

In order to be considered for selection, an interested laboratory must submit a proposal that responds to the following questions. Responses should be limited to no more than four double-spaced pages (font size \geq 11pt and page margins of \geq 1 inch) and must comply with submission requirements set out in the [Additional Information and Deadlines for Application Submission](#) below.

1. **Please describe the laboratory's current MALDI-TOF testing practices including pathogens detected.**
 - a. Describe how many years the MALDI-TOF has been in use, which MALDI-TOF is in use, how often testing is performed, pathogens tested, and amount of experience laboratory staff have in using the methodology (years, training, and consistency performing method).

2. **Please describe the laboratory's experience in testing for *N. gonorrhoeae* including methodologies.**
 - a. Describe how many years each method has been in use, how often testing is performed (times per week), annual volume, and amount of experience laboratory staff have in using the methodology (years, training, and consistency performing method).
3. **Please describe the current methodologies for testing non-gonococcal *Neisseria* species.**
 - a. Describe how many years each method has been in use, how often testing is performed (times per week), pathogens detected, and amount of experience laboratory staff have in using the methodology (years, training, and consistency performing method).
 - b. Describe current strategies to mitigate biosafety risk of working with *Neisseria meningitidis*.
4. **Please describe the current collection of non-gonococcal *Neisseria* species.**
 - a. Provide an Excel list of commensal *Neisseria* species as well as *M. catarrhalis* and *K. denitrificans* your lab currently have on hand, when possible include the number of isolates for each species, and describe the storage method (frozen, lyophilize).
5. **Include a completed and signed copy of [Appendix B](#) as an attachment.**

Additional Information and Deadlines for Application Submission

All questions should be directed to Anne Gaynor at anne.gaynor@aphl.org. Questions received from interested PHLs, together with the answers provided by APHL or CDC staff will be posted to APHL's procurement website (www.aphl.org/rfp).

Applications should be submitted to Anne Gaynor at APHL (Anne.Gaynor@aphl.org; 8515 Georgia Ave Suite 700, Silver Spring, MD, 20910; telephone: 240-485-2739; fax: 240-485-2700).

Applications must be received at APHL, attention Anne Gaynor by close of business (5:00pm ET) August 16, 2017. Either electronic or physical submission is acceptable. APHL will send an email acknowledging the receipt of your application; if you do not receive an acknowledgement within 48 hours, call 240-485-2739 to confirm receipt.

Appendix A: Expectations for the MALDI-TOF validation of *N. gonorrhoeae*

Methods

- 1) Each site will participate in a workgroup to critically review the literature of using the MALDI-TOF for the identification of *N. gonorrhoeae* and develop a standard robust validation panel. This communication will be by email and two conference calls.
- 2) Selected laboratories will collaborate with CDC to collect bacterial isolates for the validation panel. These isolates will be shipped to CDC for confirmation of bacterial identity.
- 3) CDC will prepare the validation panel by blind coding and ship to the awardee laboratories for testing on the MALDI-TOF. Selected laboratories will perform testing on the identical validation panels. Results will be transmitted back to CDC within one month.

Procurement

Supplies, Reagents and Equipment can be procured using the funding for this project. Each site will only be funded up to \$5,000 and allocation of those funds is at the discretion of the awarded sites.

Data Management

APHL will provide data collection sheets to the awardees. Data will be sent to CDC to analyze the results from the five laboratories.

Performance Management and Evaluation

Performance will be monitored by timeliness of responses to CDC and APHL requests and successful completion of the validation panel.

Reports

The laboratory will submit to APHL and CDC comments on the validation panel and results following testing. APHL and CDC will prepare a final report and a manuscript for publication in a peer reviewed journal. Each awardee laboratory will be offered to add one co-author to the manuscript.

Site visits and teleconferences

APHL, CDC and the awardee laboratories will participate in teleconferences to discuss the validation panel and address any barriers.

Appendix B: Minimum Requirements for the Validation of the MALDI-TOF for the Identification of *Neisseria gonorrhoeae* RFP

YES	NO	MINIMUM REQUIREMENT
		Does your laboratory have unrestricted access to a MALDI-TOF instrument?
		Does your laboratory have demonstrated competence and capacity using a MALDI-TOF for bacterial identification?
		Does your laboratory have demonstrated competence and capacity for bacterial culture including <i>Neisseria</i> species but not limited to <i>N. gonorrhoeae</i> ?
		Does your laboratory have sufficient equipment, laboratory space and workforce capacity for the proposed work?

Signature: _____

Date: _____

Printed Name:

Appendix C: Validation of the MALDI-TOF for the Identification of *N. gonorrhoeae* RFP Score Card

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

Category	Maximum Value	Score	Comments (REQUIRED)
<p>1. Does the applicant have sufficient capacity and experience to perform bacterial identification using MALDI-TOF?</p> <p>Excellent: Has performed bacterial identification using a MALDI-TOF for >3 years, performs bacterial identification using a MALDI-TOF least 1x per week, all staff is highly experienced in method (27-35); High: Has performed bacterial identification using a MALDI-TOF for 1-3 years, and performs bacterial identification using a MALDI-TOF at least 1x per week, most staff is experienced in method, (18-26); Moderate: Has performed bacterial identification using a MALDI-TOF for 1-3 years, and performs bacterial identification using a MALDI-TOF less than 1x per week, some staff is experienced in method (9-17); Limited: has bacterial identification using a MALDI-TOF <1 year and/or performs bacterial identification using a MALDI-TOF less than 1x per week, staff has limited experience (1-8)</p> <p>No experience = 0</p>	35		Type comments here. (REQUIRED)
<p>2. Does the applicant have sufficient experience testing for <i>Neisseria</i> sp. from different anatomical sites, and capacity to maintain long-term archive of <i>Neisseria</i> species?</p> <p>Excellent: Has performed <i>Neisseria</i> sp. identification using culture and other methods for >3 years, at least 1x per week and has stored the isolates, all staff is highly experienced in methods (27-35); High: Has performed <i>Neisseria</i> sp. identification using culture and other methods at least 1x per week for 1-3 years and has stored the isolates, (18-26); Moderate: Has performed <i>Neisseria</i> sp. identification using culture and other methods at least 1x per month for 1-3 years and has stored the isolates, some staff is experienced in method (9-17); Limited: Has performed <i>Neisseria</i> sp. identification using culture and other methods at least 4x per year for 1-3 years and has stored the isolates, some staff is experienced in method (1-8);</p> <p>No experience = 0</p>	35		Type comments here. (REQUIRED)

<p>3. Does the applicant have sufficient experience for testing non-gonococcal <i>Neisseria sp.</i>?</p> <p>Excellent: Has performed non-gonococcal <i>Neisseria sp.</i> detection using culture and other methods at least 1x per week for >3 years, all staff is highly experienced in methods (12-15); High: Has performed non-gonococcal <i>Neisseria sp.</i> detection at least 1x per week for 1-3 years, most staff is experienced in method, (8-11); Moderate: Has performed non-gonococcal <i>Neisseria sp.</i> detection at least 1x per month for 1-3 years, most staff is experienced in method (4-7); Limited: Has performed non-gonococcal <i>Neisseria sp.</i> detection at least 4x per year for 1-3 years, most staff is experienced in method (1-3); No experience = 0</p>	15		Type comments here. (REQUIRED)
<p>4. Does the applicant provide a list of commensal <i>Neisseria</i> species as well as <i>M. catarrhalis</i> and <i>K. denitrificans</i> your lab currently have on hand, when possible include the number of isolates for each species, and describe the storage method (frozen, lyophilize). Yes =15, No = 0</p>	15		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).

*Approved and adopted by the Board of Directors on June 10, 2017
Effective July 1, 2017*

Please send the Letter of Intent (Due 7/31/17) and completed application (Due 8/16/17)
to Anne Gaynor, anne.gaynor@aphl.org

APHL Conflict of Interest Disclosure Statement

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.

APHL Conflict of Interest Disclosure Statement

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.