

# Request for Proposals (RFP): Peer Network Resource Centers for New RUSP Disorders

Letter of Intent Due Date: October 19, 2016 by 5:00 pm ET

Application Due Date: November 18, 2016 by 5:00 pm ET

Technical Assistance Webinar: October 18, 2016 at 3:00 pm ET

Submit to: Sikha Singh, Manager, NewSTEPS ([sikha.singh@aphl.org](mailto:sikha.singh@aphl.org))

*The development of this request for proposals application was supported by Cooperative Agreement Number UG9MC30369 from the Health Resources and Services Administration (HRSA). Its contents are solely the responsibility of the authors and do not necessarily represent the official views of HRSA.*

Please send completed application to Sikha Singh, [sikha.singh@aphl.org](mailto:sikha.singh@aphl.org), 240.485.2726 by November 18, 2016.

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## SUMMARY

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The Newborn Screening Technical assistance and Evaluation Program (NewSTEPS), a program of the Association of Public Health Laboratories, Inc. (APHL) in collaboration with the University of Colorado School of Public Health (ColoradoSPH), is looking to identify up to three state newborn screening (NBS) programs (NBS Programs) or laboratories affiliated with NBS Programs to serve as Peer Network Resource Centers (PNRC) and provide technical assistance and/or first- and/or second- tier screening of Pompe, Mucopolysaccharidosis I (MPS-1) and X-linked Adrenoleukodystrophy (x-ALD), described in more detail in the Background section. APHL uses the term “New Disorders” in this RFP to refer collectively to these three disorders.

APHL anticipates that (1) each PNRC would receive up to \$60,000 per year for the services it renders in support of the program and (2) the program will be funded for a two-year project period.

Qualified applicants must demonstrate full implementation of first- and/or second- tier newborn dried bloodspot screening for at least one of the three New Disorders added to the Recommended Uniform Screening Panel (RUSP) by March 1, 2017. In addition, successful applicants must have a comprehensive approach to the laboratory testing, reporting, follow-up, and referral to clinical networks such that they can provide short-term to long-term technical assistance in any of these areas.

## BACKGROUND

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Public health programs in the US screen approximately 4 million newborns for at least 26 conditions every year. While the Health and Human Services (HHS) Secretary’s Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC) recommends conditions to be included on RUSP, each state determines the specific conditions for which it screens. To be effective and successful, the NBS system requires the capability to detect conditions accurately, to provide education and training, and to refer newborns for treatment upon identification of condition.

Pompe newborn screening was added to the RUSP in March 2015 and X-linked Adrenoleukodystrophy (X-ALD) and Mucopolysaccharidosis I (MPS-1) were added in February 2016. As of October 1, 2016, five states are screening for Pompe, four states are screening for MPS-1, and three states are screening for X-ALD. Details regarding states’ implementation of RUSP conditions are available at [www.newsteps.org](http://www.newsteps.org).

The HHS’ Health Resources and Services Administration (HRSA), Maternal and Child Health Bureau, Genetic Services Branch awarded Cooperative Agreement #UG9MC30369 (the Cooperative Agreement) to APHL in order to enhance, improve or expand the ability of state and local public health agencies to screen for the New Disorders as part of their newborn screening program. The Cooperative Agreement also seeks to provide health care professionals and newborn screening laboratory personnel with education and training in newborn screening for the New Disorders, and support the development and dissemination of appropriate education and training materials. APHL’s collaborative partnership with ColoradoSPH, Baby’s First Test and the Newborn Screening Translational Research Network (NBSTRN) supports the goals of the Cooperative Agreement and provides resources, education and training materials related to the New Disorders. The activities under this Cooperative Agreement are being performed in close collaboration with NewSTEPS, which is funded under Cooperative Agreement #U22MC24078 from HRSA.

The key deliverables of the Cooperative Agreement include moving states who have not yet fully implemented newborn screening for Pompe, MPS-1 and/or X-ALD closer to full implementation.

To facilitate a network of experts that can assist NBS Programs in implementing screening for the conditions, APHL is looking to identify PNRs who will serve as content area experts on laboratory techniques, follow-up procedures, and other new condition related activities, and offer training on disorder implementation. Further, the PNRs may offer first- and/or second-phase testing within their laboratories in order to facilitate implementation of screening in other states.

## ELIGIBILITY CRITERIA AND OVERVIEW OF ANTICIPATED WORK

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***NBS Programs or their affiliated or associated laboratories with an ability to perform at least two of the following three activities are eligible to apply:***

- 1) Serve as content area experts and provide technical assistance to state newborn screening programs on the implementation of laboratory techniques, follow-up procedures, and other activities specifically associated with the implementation of screening for Pompe and/or MPS-1 and/or x-ALD. This may include hosting onsite visits by other newborn screening programs to receive training and mentorship on laboratory practices and/or follow-up processes associated with implementation of screening for at least one of the new conditions.
- 2) Offer first tier screening for the new disorders for other state newborn screening programs, demonstrating capacity to increase the number of specimens screened for the selected disorder(s). Screening for other programs could be short-term, in order to facilitate earlier testing by a state program, or long-term with the intent of providing screening results for a given disorder on an ongoing basis. First-tier screening in a Peer Network Resource Laboratory may be selected on a short-term basis by state programs who are unable to complete the laboratory validation and set-up but are otherwise ready to implement the screen. Covering costs associated with a Peer Network Resource Laboratory performing laboratory screening for another program will be the responsibility of the requesting program. Funding provided through this award mechanism is intended to support the development of the infrastructure to allow additional testing.
- 3) Offer second tier/confirmatory testing (molecular/next-generation sequencing) following a positive first-tier newborn screen to other newborn screening programs. Currently, the low volume of second-tier screening in newborn screening programs makes it impractical to establish confirmatory (next generation sequencing) capabilities in all laboratories. Covering costs associated with a Peer Network Resource Laboratory performing laboratory screening for another program will be the responsibility of the requesting program. Funding provided through this award mechanism is intended to support the development of the infrastructure to allow additional testing.

## RFP SCHEDULE

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October 11, 2016	–	RFP Issued
October 18, 2016	–	Technical Assistance Webinar at 3:00 pm ET (see NewSTEPS listserv for webinar details)
October 19, 2016	–	Letter of intent due by 5:00 pm ET to APHL (see the <a href="#">Letter of Intent</a> section below)
<b>November 18, 2016</b>	–	<b>RFP responses due</b> by 5:00 pm ET to APHL
December 9, 2016	–	Awardees notified
February 1, 2016	–	Contracts ratified between APHL and awardees

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

## RFP PROCESS OVERVIEW

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### Letter of Intent

APHL requests that prospective applicants must submit a brief email statement indicating a firm intent to submit a proposal by no later than the RFP Due Date. Although a letter of intent is not binding, and does not enter into the review of the RFP, the information that it contains allows APHL staff to estimate the potential review workload and plan the contract development and review process. Potential applicants must include the name of the organization or individual that will submit the proposal in their email.

The prospective bidders should email a statement reflecting the intent to apply to the contact identified in the

Submission of RFP section below using the subject line: LETTER OF INTENT: PEER NETWORK RESOURCE CENTERS RFP. APHL must receive this information by **5:00 pm ET on October 19, 2016.**

## Submission of RFP

**Applications must be received at APHL, attention Sikha Singh by close of business (5:00 pm ET) November 18, 2016.** Either electronic or physical submission is acceptable, but electronic submissions preferred. APHL will send an email acknowledging the receipt of your application; if you do not receive an acknowledgement within 48 hours, call 240.485.2726 to confirm receipt.

Physical applications must be sent to the following address:

Sikha Singh  
Manager, NewSTEPS  
Association of Public Health Laboratories  
8515 Georgia Avenue, Suite 700  
Silver Spring, MD, 20910  
Telephone: 240.485.2726  
Fax: 240.485.7000

Electronic submissions must be sent to Sikha Singh at [sikha.singh@aphl.org](mailto:sikha.singh@aphl.org) with a copy to [newsteps@aphl.org](mailto:newsteps@aphl.org)

## TECHNICAL ASSISTANCE WEBINAR

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**Date:** Tuesday, October 18, 2016

**Time:** 3:00 pm ET

**Duration:** 1 hour

**Dial-In:** 866.740.1260 | Access Code: 4852701

**Web Login:** <https://cc.readytalk.com/r/eiiz46mc90dq&eom>

## RESPONSE REQUIREMENTS

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Each complete response packet must include:

- Section 1: Response to Questions
- Section 2: Budget and Budget Justification
- Section 3: Sustainability Plan

## SECTION 1: QUESTIONS

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**Programs submitting material for consideration must answer the following questions in their proposal.** Responses should be limited to no more than 20 double-spaced pages (font size of 11 point or larger and page margins of at least an inch). In addition, programs may submit CVs of key personnel as an appendix to their proposal. A budget, budget justification and sustainability plan is also required.

Your application will not be reviewed without the pieces noted above.

*When did (will) your program initiate screening for each of the following disorders, and what methodology is (or will be) used?*

**a. Pompe Disease**

Date:

Methodology:

Comments:

Not applicable (no plan in place to screen for Pompe):

**b. MPS-I**

Date:

Methodology:

Comments:

Not applicable (no plan in place to screen for MPS-I):

**c. X-ALD**

Date:

Methodology:

Comments:

Not applicable (no plan in place to screen for X-ALD):



*Describe your program's capabilities to provide technical assistance.*

List laboratory, follow-up (short- and long-term), education, and clinical expertise that would be used to provide technical assistance to states newly adopting one or more of the new disorders. In your description, please speak to how laboratory, follow-up, and clinical experts work together to identify and connect families to clinical networks (include communication, access to reporting, and referral process). Provide staff names and experience in providing training and technical assistance and identify the disorders for which you will be able to provide technical assistance.

Your response should include experience of the program and the staff identified in presenting to large groups on methods or approaches, experience training others onsite (laboratory and follow-up), and experience visiting other sites to provide training or technical assistance. Please also describe your willingness and ability to serve as an expert resource to assist other programs in adding conditions to their local screening panels, and the resources you have in place to assist.

Finally, describe the educational materials (if any) you have for families, providers, or the general public on Pompe, X-ALD, or MPS-1 and how you distribute these materials. Also, if applicable, describe the system you use to track the impact of your education efforts around the new disorders.

*Describe your laboratory's capability and maximum capacity to provide first tier and/or second tier screening for each of the New Disorders.*

Responses should include the instrumentation used, cost per specimen, and turn-around time from receipt of specimen to results reporting. Please also address how you have performed testing for other programs in the past (if applicable), and describe turn-around time, results reporting, whether there is a system in place to bill other programs (and if not when will the system be in place).

Please describe the educational resources you have in place for parents, primary care physicians, and the general public for each disorder.

Explain how you are building infrastructure so that after the award funding stops you can continue to assist other states with Tier 1 and Molecular and/or Next Generation Sequencing and/or continue provide technical assistance.

## SECTION 2: UTILIZATION OF FUNDS | BUDGET AND BUDGET JUSTIFICATION

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Please include a budget (and budget justification) of *up to* \$60,000. Each component of the budget will be evaluated as it supports the two- to three- activities proposed. Budgets should be commensurate with the activities proposed. Your application will not be reviewed without this piece.

### Technical Assistance

Support technical assistance via participation in webinars (supported by NewSTEPS) and phone calls, as well as hosting newborn screening program site visits and in-person meetings. Funded PNRs will host one in-person meeting that will incorporate laboratory, follow-up and clinical experts in order to help other newborn screening programs implement screening for new disorders. *Please note:* travel and lodging will be funded by NewSTEPS; with the Peer Network Resource Center hosting a training and/or meetings in its laboratory and follow-up program and being responsible for consumable costs and staff time associated with the training/meeting.

### Screening, Reporting, and Billing Infrastructure

Establish the infrastructure to perform either first- and/or second- tier laboratory screening for one or more of the new disorders. States programs that choose to utilize peer laboratories for screening will be expected to pay for that screening utilizing a mechanism outside of the NewSTEPS funding; NewSTEPS funding will contribute to the development of the infrastructure to increase capacity to screen, report, and bill for the additional testing. The Peer Network Resource Center will be required to demonstrate sustainability by the end of the funding period.

## SECTION 3: SUSTAINABILITY PLAN

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Please include an explanation of how the approach outlined will be sustained following the funding allowance/period. Your application will not be reviewed without this piece.

## EVALUATION OF RESPONSES

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### Initial Review

NewSTEPs program staff will conduct an initial review of all proposals for completeness. Any application that is incomplete on the RFP Due Date (see RFP above) will not be considered and will not receive a formal evaluation.

### Evaluation Team

After the initial review, an evaluation team will be assembled to evaluate competitive proposals and then assess their relative qualities based on the Evaluation Criteria outlined below and any other factors noted in this RFP. This evaluation team will consist of at least 2 Subject Matter Experts (SMEs) familiar with disorder implementation. The SMEs may consist of APHL members or other external individuals that have expertise in the content area. In addition, the review team may include ColoradoSPH or HRSA employees, SMEs with whom APHL or ColoradoSPH has previously worked, or other SMEs referred to APHL by ColoradoSPH, HRSA or one of the association's members. APHL's Senior Director for Public Health Systems will have final approval over the selected review team's composition.

APHL will ask proposed review committee members to disclose any potential conflict of interest and APHL will not place any individual with a conflict of interest on the evaluation team. In the event that a reviewer identifies a conflict of interest (or if APHL staff have reason to believe that a reviewer may not be impartial) after the evaluation team has been assembled, APHL will exclude that reviewer from further participation in the review process and will eliminate that reviewer's completed reviews from the evaluation process.

### Evaluation Criteria

The evaluation team will score the proposals based on a uniform rubric, with reviews conducted by phone call convening both internal and external reviewers.

Scoring will occur by condition (Technical Assistance and first-tier screening) as well as by ability to perform Next Generation Sequencing/Molecular techniques. Partial credit will be provided. Programs with the highest scores for **each disorder** that can facilitate screening for more than one disorder may be given preference. Scoring criteria are found below. A detailed scoring rubric will be made available upon request and will be further explained during the Technical Assistance National Webinar scheduled for October 18, 2016 at 3:00 pm ET.

Scoring Criteria and Points	
Scoring Criteria	Points
Experience Screening	10 points for each disorder
Technical Assistance Abilities	10 points for each disorder
Reporting and Billing Infrastructure	10 points for each disorder
General Technical Assistance Abilities	15 points
First Tier Testing Experience for Other States	5 points
Molecular/Next Gen Sequencing Experience	20 points
Sustainability Plan	5 points
Budget/Utilization of Funds	5 points

## POST-EVALUATION PROCEDURES

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The selected awardees will be notified by APHL program staff by December 9, 2016 and the names of the selected programs will be posted to APHL's procurement website, [www.aphl.org/rfp](http://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 selected awardees is posted.

All applicants 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.

## AWARD

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Up to three programs, depending on the strength of applications, will be selected. Each selected site will be eligible for an award of up to \$60,000 per year for two years which will be distributed via a contract administered by APHL.

## TERM OF PROJECT

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The project term will be from date of contract signing (approximately February 1, 2017) through August 31, 2017. APHL anticipates the potential for one additional annual renewal (running from September 1, 2017 to August 31, 2018). 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 HRSA programmatic requests in that funding year. Each selected project would be notified in advance of any modification to the anticipated scope of work in a future funding year.

## CONDITIONS OF AWARD ACCEPTANCE

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The eligible applicants 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 applicant.

Prior to making the official award, a group of individuals from HRSA, APHL or ColoradoSPH will have the option to elect to tour an applicant's facilities to assess its capacity to serve in as a PNRC. Post award, APHL staff, members or contractors/consultants may conduct monitoring site visits in order to assess continued compliance.

## RFP-RELATED QUESTIONS

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All questions should be directed to Sikha Singh at [sikha.singh@aphl.org](mailto:sikha.singh@aphl.org). Questions received from interested parties, together with the answers provided by APHL, ColoradoSPH or HRSA staff will be posted to APHL's procurement website ([www.aphl.org/rfp](http://www.aphl.org/rfp)).

## DISCLAIMER AND OTHER GENERAL MATTERS

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This RFP is neither an agreement nor an offer to enter into an agreement with any respondent. Once evaluation is complete, APHL may choose to enter into a definitive contract with the selected RFP applicant(s).

APHL must ensure that the selected applicant(s) are neither suspended nor debarred from receiving federal funds and that the applicant(s) meet any other funding eligibility requirement imposed by the Cooperative Agreement. APHL's determination of whether the applicant is eligible to receive Cooperative Agreement funding will be definitive and may not be appealed. In the event that APHL determines that the selected applicant(s) is ineligible to receive Cooperative Agreement funding, APHL will nullify the contract or will cease negotiation of contract terms.

Each applicant will bear its own costs associated with or relating to the preparation and submission of its application. These costs and expenses will remain with the applicant, and APHL will not be liable for these or for any other costs or other expenses incurred by the applicant in preparation or submission of its application, regardless of the conduct or outcome of the response period or the selection process.