

RFP Number: WC-2019-01

HEALTH RESEARCH, INC.

New York State Department of Health  
Wadsworth Center  
Division of Infectious Diseases

Request for Proposals

A point-of-care device for the detection of *Candida auris*

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KEY DATES

|                                    |  |
|------------------------------------|--|
| RFP Release Date:                  | August 1, 2019   |
| Letter of Interest:                | August 22, 2019 by 5.00pm EST (optional)                     |
| Questions Due:                     | August 22, 2019 by 5.00pm EST                                |
| RFP Q&A Posted:                    | September 5, 2019  |
| Proposals Due:                     | October 3 <sup>rd</sup> , 2019 by 5.00pm EST                 |
| Awardees Notified:                 | Anticipated mid-November, 2019                               |
| Earliest date for project funding: | January 2 <sup>nd</sup> , 2020 or when contracts are signed. |

Contact Information: [DOH.sm.C.auris@health.ny.gov](mailto:DOH.sm.C.auris@health.ny.gov)

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## I. Introduction

The Wadsworth Center is New York State's public health laboratory and it serves a vital role in the New York State Department of Health's efforts to protect and promote the health of New Yorkers. The Wadsworth Center, whose mission is "Science in Pursuit of Health," occupies a unique niche as a premier biomedical institute that merges clinical and environmental testing with fundamental, applied and translational research. Today, Wadsworth Center scientists use both classical and contemporary approaches to study environmental and biological questions related to human health and disease. They develop, optimize and validate advanced methods to identify microbial or chemical threats; study drug resistance, emerging infections, and environmental exposures; manage the country's most comprehensive diagnostic and environmental testing laboratory permit program; oversee extramural research programs on stem cells, breast cancer and spinal cord injury; and train the next generation of scientists through undergraduate, graduate, postdoctoral and visiting scientist programs.

The Wadsworth Center's core functions are:

- Screening all 250,000 newborns in New York State for 50 treatable conditions;
- Performing sophisticated testing to detect infectious disease agents and environmental toxins;
- Protecting the public against terrorist threats;
- Assuring that all laboratory assays performed on New York State patients are of the highest quality by inspecting commercial and hospital laboratories and identifying deficiencies;
- Conducting basic and applied research to develop cures for diseases and to support regulatory and public health functions;
- Promoting economic development in New York by administering extramural grant programs such as the New York State Stem Cell Research Program;
- Training the future laboratory workforce through educational programs for undergraduate and graduate students;
- Responding to emerging threats such as *Bacillus anthracis*, SARS, MERS, pandemic influenza, Ebola, and *Legionella* as well as the current concerns of measles virus, *Candida auris*, Perfluorooctanoic acid (PFOA), and synthetic cannabinoids.

More information about the Center can be found at <http://www.wadsworth.org>.

Health Research, Inc. (HRI) is an independent, private, not-for-profit corporation qualified under sec. 501(c)(3) of the IRS Code. It is legally recognized by New York State as a "Research Institute" and a "State Affiliated Corporation" in State Finance Law (Section 53-a, State Finance Law).

HRI's primary purpose is to provide a vehicle through which scientists and public health professionals can successfully compete for extramural grants to supplement their research and public health programs. Clients include New York State Department of Health (NYSDOH), Roswell Park Cancer Institute, and related outside organizations, both public and private. The flexibility, speed and expertise provided by HRI are

essential in attracting and securing this external grant funding in a highly competitive environment.

HRI conducts, encourages and supports extensive studies and research into the causes, nature and treatment of diseases, disorders and defects of particular importance to the public health. HRI's work aligns with the purposes and objectives of the NYSDOH and its associated institutions and agencies, including Roswell Park Cancer Institute and other entities engaged in health-related matters. HRI is an active partner with the ability to quickly recruit and hire qualified candidates to carry out both basic and applied research in all fields of the arts and sciences, and to execute contracts to assist its clients to carry out research or public health initiatives. More information can be found at <https://www.healthresearch.org/about-hri/mission-vision-values/>.

### **Establishing the purpose of this RFP**

Infectious disease testing is being revolutionized by point-of-care diagnostic devices. These devices are being developed for use in healthcare facilities as well as for over-the-counter sale in pharmacies. The revolution is driven in part by advances in micro- and nanoscale technology enabling the development of microfluidic and microelectronic devices. By and large, these devices are good but do not yet achieve the sensitivity and accuracy obtained with larger and more complex instruments or traditional 'gold standard' tests.

*C. auris* is an emerging fungal pathogen that presents a serious global health threat. The pathogen is often multidrug-resistant, meaning that it is resistant to multiple drugs commonly used to treat fungal infections. *C. auris* is difficult to identify with standard laboratory methods, and it can be misidentified in laboratories without special technology. *C. auris* misidentification may lead to inappropriate patient management, which can result in the spread of the disease.

*C. auris* was first identified in New York State in 2016. As of June 25, 2019 there were 339 clinical cases and 494 screening cases reported to the NYSDOH ([https://www.health.ny.gov/diseases/communicable/c\\_auris/](https://www.health.ny.gov/diseases/communicable/c_auris/)). As of July 12, 2019, the national clinical case count is 716 across 12 states with nearly 90% of cases in NY, NJ, and IL (<https://www.cdc.gov/fungal/candida-auris/index.html>). CDC reports include an additional 1,342 patients found colonized with *C. auris* by targeted screening in ten states. *C. auris* cases have also been reported from several countries on different continents including 620 cases from six European Union countries for the period 2013–2017 (<https://ecdc.europa.eu/sites/portal/files/documents/RRA-Candida-auris-European-Union-countries.pdf>).

Clinical cases are people who are ill from the fungal pathogen. Screening cases are people who are not ill but who carry the pathogen on their skin and are identified as part of our surveillance efforts. These cases can lead to spread of the fungal pathogen throughout a hospital or healthcare unit.

Most outbreaks of *C. auris* occur in healthcare settings, and infection is almost exclusively seen in people with complex healthcare needs, such as residents of nursing homes who require long term ventilator support and people with multiple ICU admissions. For this reason, it is important to quickly identify *C. auris* so that healthcare facilities can take special precautions to prevent its spread.

To date, over 15,000 samples from nearly 200 facilities have been tested by the Wadsworth Center, NYSDOH. The Wadsworth Center *C. auris* real-time PCR laboratory developed test (LDT) has been crucial in the surveillance effort. However, LDT adoption in other laboratories is slow, and it is unlikely to meet the demands for expanded testing. The scope and complexity of this emerging pathogen require more healthcare facilities to perform *C. auris* testing to impact infection control and prevention measures.

## **Project Scope**

The goal of this project is to design and construct a working prototype for a low complexity point-of-care device for the detection of *C. auris* in healthcare facilities. Awardees will develop a working prototype that is portable, rapid, cost-effective, and can be independently evaluated for analytical performance. It is, however, not expected that this device will be “manufacture ready.” The amount of the individual award will be a maximum of \$250,000 over an 18-month period. HRI will award up to 3 contracts.

## **II. Who May Apply**

US-based firms and organizations that:

1. Have the facilities and capability to provide the product identified in the Project Scope.
2. Will work closely with the Center to evaluate and optimize the prototype device.
3. Will negotiate with HRI regarding shared ownership of Intellectual Property.
4. Preferably have experience in developing devices for infectious agents.

## **III. Project Narrative/ Work Plan Outcomes**

### **A. Minimum performance requirements**

The minimum performance requirements for a low complexity portable point-of-care device for detecting *C. auris* from patient swabs (from nares, axilla, groin or other body

sites) and/or other collection devices are:

- Sensitivity - The device must be able to detect 100 or less colony-forming units in the specimen matrix.
- Specificity - Specificity is expected to be >95% when tested against other relevant infectious agents.
- Accuracy - Blinded accuracy studies using varying concentrations of *C. auris* in the specimen matrix should provide >90% accuracy.
- Reproducibility - The assay should be >90% reproducible when tested repeatedly at a level of target approximately 10-fold above the Limit of Detection.
- Time to result - Results should be determined within 2 hours or less from initiation of the test.
- Inhibition - The device should exhibit no inhibition from other materials such as antiperspirants, moisturizers, etc.

**B. Additional desirable features include:**

- The device can interface with a Laboratory Information System.
- The device displays the final result without requiring human interpretation.
- The device will allow future expansion to detect other infectious agents.
- The device can be developed into a low-cost final version.

**IV. Administrative Requirements**

**A. Issuing Agency**

This RFP is issued by the NYSDOH, Wadsworth Center, Division of Infectious Diseases and HRI with funding provided by HRI. NYSDOH/HRI are responsible for the requirements specified herein and for the evaluation of all proposals.

**B. Question and Answer Phase:**

All questions must be submitted in writing to the following email by 5:00 pm EST August 22<sup>nd</sup>, 2019:

[DOH.sm.C.auris@health.ny.gov](mailto:DOH.sm.C.auris@health.ny.gov)

To the degree possible, each inquiry should cite the RFP section and paragraph to which it refers. Written questions will be accepted until the date posted on the cover of this RFP.

Prospective applicants should note that all requests for clarification and exceptions, including those relating to the terms and conditions of the contract, must be raised prior to the submission of a proposal.

This RFP has been posted on the Wadsworth and HRI websites at:

<https://www.wadsworth.org/node/76791>

<http://www.healthresearch.org/funding-opportunities>.

Questions and answers, as well as any updates and/or modifications, will also be posted on those websites. All such updates will be posted by the date identified on the cover sheet of this RFP.

If prospective applicants would like to receive notification when updates/modifications are posted (including responses to written questions) please complete and submit a letter of interest and send it to [DOH.sm.C.auris@health.ny.gov](mailto:DOH.sm.C.auris@health.ny.gov). Submission of a letter of interest is not a requirement for submitting a proposal; however, it will help us plan for the review phase.

### **C. Applicant Conference**

An Applicant Conference will not be held for this project.

### **D. How to file a proposal**

Proposals must be **received** at the following address by 5:00 pm EST on Thursday October 3<sup>rd</sup>, 2019: [DOH.sm.C.auris@health.ny.gov](mailto:DOH.sm.C.auris@health.ny.gov). Late proposals will not be accepted.

The email with the proposal package as an attachment should be clearly labeled in the subject line with the name and number of the RFP as listed on the cover of this RFP document.

It is the applicant's responsibility to verify that the proposal is delivered to the address above prior to the date and time specified above.

### **E. HRI and WADSWORTH CENTER'S RESERVED RIGHTS**

1. Reject any or all proposals received in response to this RFP.
2. Withdraw the RFP at any time, at their sole discretion.
3. Make one or more awards under the RFP in whole or in part.
4. Disqualify any applicant whose conduct and/or proposal fails to conform to the requirements of the RFP.

5. Seek clarifications and revisions of proposals.
6. Use proposal information obtained through site visits, management interviews and the state's investigation of an applicant's qualifications, experience, ability or financial standing, and any material or information submitted by the applicant in response to the agency's request for clarifying information in the course of evaluation and/or selection under the RFP.
7. Prior to bid opening, amend the RFP specifications to correct errors or oversights, or to supply additional information as it becomes available.
8. Prior to proposal opening, direct applicants to submit proposal modifications addressing subsequent RFP amendments.
9. Change any of the scheduled dates.
10. Waive any requirements that are not material.
11. Award more than one contract resulting from this RFP.
12. Conduct contract negotiations with the next responsible applicant, should HRI be unsuccessful in negotiating with the selected applicant(s).
13. Unless otherwise specified in the RFP, every offer is firm and not revocable for a period of 60 days from the bid opening.
14. Waive or modify minor irregularities in proposals received after prior notification to the applicant.
15. Require clarification at any time during the procurement process and/or require correction of arithmetic or other apparent errors for the purpose of assuring a full and complete understanding of an offerer's proposal and/or to determine an offerer's compliance with the requirements of the RFP.
16. Negotiate with successful applicants within the scope of the RFP in the best interests of HRI.
17. Eliminate any mandatory, non-material specifications that cannot be complied with by all applicants.
18. Award contracts based on geographic or regional considerations to serve the best interests of HRI.

**F. Term of Contract**

Any contract resulting from this RFP will be effective only upon approval by HRI.

It is expected that contracts resulting from this RFP will have the following time period: 18 months. Extensions may be granted subject to satisfactory performance. Renewals may be possible dependent on availability of continued funding.

#### **G. Payment and Reporting Requirements**

1. The contractor shall submit invoices and required reports to: Dr. Jill Taylor at [DOH.sm.C.auris@health.ny.gov](mailto:DOH.sm.C.auris@health.ny.gov).
2. Once the contract period begins, it is expected that the awardee will maintain close communication via conference calls, in-person meetings and site visits with the Scientific Director of this project, Dr. Vishnu Chaturvedi ([vishnu.chaturvedi@health.ny.gov](mailto:vishnu.chaturvedi@health.ny.gov)), and submit monthly written progress reports. In addition, a formal final report at 18 months or at the termination of the contract is required.

All payment and reporting requirements will be detailed in the final contract.

#### **H. General Specifications**

1. By signing the "Proposal Form" each applicant attests to their express authority to sign on behalf of the applicant.
2. Contractor will possess, at no cost to HRI or the State, all qualifications, licenses and permits to engage in the required business as may be required within the jurisdiction where the work specified is to be performed. Workers to be employed in the performance of this contract will possess the qualifications, training, licenses and permits as may be required within such jurisdiction.
3. Submission of a proposal indicates the applicant's acceptance of all conditions and terms contained in this RFP, including the terms and conditions of the contract. Any exceptions allowed by HRI during the Question and Answer Phase (Section IV.B.) must be clearly noted in a cover letter attached to the proposal.
4. An applicant may be disqualified from receiving awards if such applicant or any subsidiary, affiliate, partner, officer, agent or principal thereof, or anyone in its employ, has previously failed to perform satisfactorily in connection with public bidding or contracts.
5. Provisions Upon Default

- a. The services to be performed by the Applicant shall be at all times subject to the direction and control of HRI as to all matters arising in connection with or relating to the contract resulting from this RFP.
  - b. In the event that the Applicant, through any cause, fails to perform any of the terms, covenants or promises of any contract resulting from this RFP, HRI shall thereupon have the right to terminate the contract by giving notice in writing of the fact and date of such termination to the Applicant.
6. Applicant must maintain an active registration in the System for Award Management (SAM) at SAM.gov, and have no exclusions or delinquent federal debt.
  7. It is expected that HRI and awardee will share in the intellectual property resulting from this project.
  8. Contract agreements will be negotiated upon selection of awardees.

## **V. Completing the Proposal**

### **A. Proposal Content/Format**

The following sections of the application should be completed within the space indicated below:

#### **1. Cover Page**

The cover page should include the title of the proposal, the name, mailing address and telephone number of the company or organization, and the technical and administrative/business contacts (name, address, phone, and e-mail address).

#### **2. Program Summary/Abstract**

In 500 words or less, summarize the proposed program, including objectives to meet the stated goals.

#### **3. Approach/Timelines (6 pages)**

The approach section should contain a detailed description of the project, innovative approach or methodology, experimental design, rationale for the experimental approach, measurable objectives or aims, and alternative approaches if the proposed methods are not successful. Previous results and data can be included to justify the proposal.

Also provide a detailed listing of tasks/subtasks organized by work timelines, and a detailed description of the deliverables for the proposed work. A Gantt chart should be included with milestones for each task.

**4. Key Personnel and pertinent experience (10 pages)**

Biographical sketches including recent experience, accomplishments related to the proposed work, and the percentage of time each individual will contribute to this project. A summary of activities related to the proposed work can be included.

**5. Organization facilities, infrastructure and other resources (2 pages)**

Brief description of the facilities that will be utilized to perform the work proposed by the applicant. Pertinent infrastructure and resources of the applicant organization should also be included in the proposal.

**6. Budget/Cost Sheet (2 pages)**

Applicant should indicate the funds that will be allocated to the categories of expenses including salary (including fringe and indirect costs), materials and supplies, instrumentation and equipment, and other costs, including travel to communicate with the Wadsworth Center/HRI or subcontractor applicable. The maximum budget is \$250,000. Once a contract is developed, quarterly payments to the contractor will be based on tasks and deliverables determined, by agreement, within the contract format.

**B. Review Process**

ALL PROPOSALS MUST CONFORM TO THE FORMAT PRESCRIBED ABOVE. PROPOSALS THAT DEVIATE FROM THE PRESCRIBED FORMAT WILL NOT BE REVIEWED.

Proposals will be reviewed and evaluated competitively by HRI and subject matter experts within the Division of Infectious Diseases and the Wadsworth Center using the scoring criteria below. The results of the scoring and reviewers' comments will be made available to the applicant at the time of the announcement of the successful applicant(s).

**Scored Review Criteria**

Reviewers will consider each of the review criteria below in the determination of scientific and technical merit, and give a separate score for each. The final score will be based upon these criteria and an evaluation of the overall impact of the proposal. An application does not need to be strong in all categories to be judged

likely to have major public health impact. For example, a project that by its nature is not innovative may be essential to advance a field.

**Significance.** How does the project address the need for development of point-of-care devices for fungal diseases? If the aims or objectives of the project are achieved, how will technical capability and/or clinical practice be improved? How will successful completion of the aims or objectives change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field? Will the developed technology be adaptable to other infectious diseases?

**Maximum score = 10**

**Investigator(s).** Are the PD/PIs, collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators, or in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and appropriate expertise?

**Maximum score = 20**

**Innovation.** Does the application challenge and seek to shift current clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to *C. auris*/fungal detection or more broadly applicable to other infectious agents? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

**Maximum score = 20**

**Approach.** Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility, and will particularly risky aspects be managed? Have appropriate performance goals been included?

**Maximum score = 25**

**Environment.** Will the environment in which the work will be done contribute to the probability of success?

**Maximum score = 25**

## **C. Award Announcement**

Selection and announcement of awardees are expected to be made by mid-November, 2019. The list of awardees will be posted on the Wadsworth Center and HRI websites.

## **D. Confidentiality**

- HRI/Wadsworth Center will treat as confidential any non-public information that is first received from the applicant in their RFP response, other than information that is also received from other, non-confidential sources, or that is independently developed.
- HRI/Wadsworth Center will not distribute the applicant's RFP response beyond its internal review committee and contract team.
- Please mark/highlight as CONFIDENTIAL and PROPRIETARY all sections containing confidential information and every page with "Not for Distribution."
- HRI/Wadsworth Center would also be willing to enter into a two-way nondisclosure agreement to protect both parties. HRI/Wadsworth Center can provide a reasonable form of agreement if necessary.
- HRI/Wadsworth Center will include suitable confidentiality provisions in the final written contract.