

HEALTH RESEARCH, INC. and New York State Department of Health

RFP #WC-2021-01 Building NYS Whole Genome Sequencing Capacity for SARS-COV-2 Partnership

Questions and Answers

May 27, 2021

Question	Subject	Bidder's Question	Answer
1	Section II, Who May Apply, pages 4-5.	How can we take part in this study?	Laboratories that meet the requirements described in Section II are eligible to apply and may submit a proposal as described in Section V by June 10, 2021. The eligibility provisions of the RFP are further clarified below. Alternate ways to participate are described in the responses to questions 5, 6, and 19.
2	Section II, Who May Apply, pages 4-5.	How do we know whether our institution is eligible to apply?	Laboratories that meet the requirements described in Section II are eligible. See response to question 1 above.
3	Section II, Who May Apply, pages 4-5.	Are laboratories outside of New York (NY) eligible to participate?	Yes. Laboratories with access to positive SARS-CoV-2 specimens from patients residing in NYS may participate.
4	Section II, Who May Apply, pages 4-5.	Is there an RFP for New York City hospital laboratories too? Are laboratories based in NYC eligible to apply?	The NYS Department of Health (NYS DOH) and Health Research, Inc (HRI) will support this whole genome sequencing (WGS) partnership with funding from the Centers for Disease Control and Prevention's (CDC), Epidemiology and Laboratory Capacity for Prevention and Control of Emerging Infectious Diseases (ELC) <i>Enhancing Detection Expansion</i> supplement. The partnership will build capacity for WGS of specimens from patients residing from all regions of the state <i>excluding NYC</i> . Laboratories located in NYC with access to positive SARS-CoV-2 specimens from NYS patients residing outside of NYC may participate.

5	General: Providing SARS-CoV-2 Specimens to other laboratories.	Our lab does not perform WGS, but could provide de-identified SARS-CoV-2 positive upper respiratory samples (from patients in the lower Hudson Valley) to one or more of the laboratories chosen to participate in this research partnership. If the NYS DOH/HRI are interested, how can we participate?	Laboratories with access to SARS-CoV-2 positive specimens may contact other laboratories who perform WGS to explore collaboration opportunities. The NYS DOH will not directly reimburse those laboratories supplying specimens to contract WGS laboratories. Contract WGS laboratories may seek reimbursement for costs associated with attainment/transfer of specimens; the NYS DOH will reimburse participating WGS laboratories at a rate of up to \$150 per sample.
6	General: Attaining SARS-CoV-2 Specimens from other laboratories. Section II, Who May Apply, pages 4-5.	We do not have access to SARS-CoV-2 positive specimens in a proposed multi-county catchment area. Would NYS DOH provide specimens to the sequencing site? Should we consider applying with this limitation or this is a requirement for this application?	<p>The NYS DOH does not plan to provide SARS-CoV-2 specimens to the participating laboratories. Laboratories are responsible for attaining samples from their catchment area. Laboratories with insufficient access to SARS-CoV-2 specimens in their proposed catchment area may consider contacting other laboratories to explore collaboration opportunities.</p> <p>To search NYS permitted clinical laboratories for Virology, visit: https://www.wadsworth.org/regulatory/clep/approved-labs The NYS DOH Wadsworth Center also posts a list of NYS permitted laboratories performing SARS-CoV-2 diagnostic testing with reported significant excess capacity for testing that can be viewed at: https://www.wadsworth.org/testing-capacity</p> <p>Please note, there may be some circumstances when the NYS DOH directs specimens to a participating laboratory for analysis. This may include specimens from unique cases including unusual disease manifestation, severity of illness, travel history, suspected therapy or vaccine evasion, or other scenarios.</p>

7	General: Attaining SARS-CoV-2 Specimens from other. Section II, Who May Apply, pages 4-5.	We have high capacity and expertise of PacBio sequencing for whole genome viral sequencing, but we do not have access to those samples. Would NYS DOH or Wadsworth Center provide those samples?	See response to question 6.
8	Section II, Who May Apply, #5, page 5. Section V. Subsection A., Proposal Content, Subsection 3, page 17.	What does “Has access” mean? Does a laboratory already have to have access to or be receiving specimens in the proposed multi-county catchment areas? Or similarly in Section V – Subsection 3 – Statement of Need, First bullet point, Page 17: This paragraph implies that the laboratory is already receiving specimens (“describe infrastructure..., quantity of specimens received by the laboratory per week, percentage of positive specimens with CT deemed appropriate...”). If a laboratory does not have to have an established source of COVID-19 specimens from the proposed catchment area(s), would the NYS DOH or Wadsworth Center direct specimens to sequencing capable and accepting laboratories?	If a facility does not have access to or sufficient access to SARS-CoV-2 positive specimens for WGS, they should seek to identify partners to provide such specimens. The current access to specimens and any planned partnerships to increase access to specimens should be described in the proposal’s Statement of Need. The NYS DOH does not plan to provide SARS-CoV-2 specimens to the participating laboratories, with exception of specimens from unique cases (see response to question 6).
9	Section III, Project Narrative, Paragraph 2, page 5	“Applicants must identify a catchment area of multiple counties...” Based on what criteria or how should a laboratory go about identifying their catchment counties?	This RFP aims to provide WGS on approximately 10% of the SARS-CoV-2 positive specimens from patients residing in upstate and Long Island NY. Applicants should aim to capture a <i>minimum</i> of 10% of SARS-CoV-2 specimens from their proposed catchment area. Proposals must describe the proposed throughput in the Program Summary.

			<p>Proposals that do not meet the 10% threshold will be considered. Additionally, proposals that exceed the 10% threshold will also be considered. The 10% threshold may be modified as SARS-CoV-2 prevalence changes over time.</p> <p>In general, laboratories may define their catchment area based on access to specimens.</p>
10	Section III, Project Narrative, pages 5-6.	Please confirm if the selected laboratories may facilitate logistics of shipping positives collected within the catchment area to a centralized facility for sequencing.	Yes, laboratories are encouraged to work with other laboratories to secure access to SARS-CoV-2 positive specimens in their multi-county catchment area. The contract WGS laboratories should facilitate logistics related to securing specimens for testing.
11	Section II, Who May Apply, pages 4-5.	May a laboratory that performs RT-PCR detection and discrimination of select SARS mutations, E484K, N501Y, and deletion HV-69/70 participate, particularly if we may be the only laboratory to cover remote populations in NYS.	<p>No. Laboratories must have capacity to perform whole genome sequencing (WGS) to participate. Please see the response to question 5.</p> <p>In addition, please note, if a laboratory performing mutation specific PCR analysis will provide positive specimens to a contract WGS laboratory – the specimens provided must be randomly selected and not selected based on a specific mutation.</p>
12	Section III, Project Narrative, page 5-6.	Is there a minimum number of samples that must be sequenced per week? Large batches will be required to get economies of scale.	No. This effort is intended to provide broad population surveillance. Applicants should aim to capture a <i>minimum</i> of 10% of SARS-CoV-2 specimens from their proposed catchment area. Testing is reported on a biweekly basis. Laboratories may choose their testing schedule within that timeframe.
13	Section III, Project Narrative, page 5.	What would the expected volume and turnaround times be?	<p>The volume of testing must factor in the population size of the catchment area and SARS-CoV-2 positivity rates (see response to question 9).</p> <p>Turnaround times (beginning from the time of sample receipt by the contract WGS laboratory) are preferred within 7 days and may extend no more</p>

			than 14 days. Please note, the NYS DOH may request that specimens from unique cases be analyzed more quickly.
14	Section III, Project Narrative, page 5.	Please confirm the desired/target turnaround time for results.	See response to question 13.
15	Attachment 4	Will we be reporting in the positivity rate per county on a regular basis?	Per Attachment 4, the positivity rate for each county in the catchment area is a required data element of the biweekly (every 2 weeks) Status Updates.
16	Section III, Project Narrative, page 6.	While the RFP indicates this would be coordinated with the selected labs, please confirm or provide any details around specific reporting formats/structure that may be requested by NYS DOH to the extent available.	Expectations for reporting are described in the RFP. The Progress Reports will be brief and streamlined to reduce redundancy with the Status Updates and data uploads. The NYS DOH is committed to provide technical assistance and support to the contract WGS laboratories to help them meet any additional NYS data submission or reporting expectations not captured in the RFP.
17	Section III, Project Narrative, page 6.	What other information will need to be collected on patients?	GISAID uploads and NYS data submissions should include age, sex, and county of residence.
18	General, Section V, subsection 2, Program Summary, page 16.	Can additional services related to, but outside of, the scope of the current RFP be documented for consideration by Wadsworth? If so, can you confirm they can be described in the Program Summary section?	Applicants may propose additional services but must, at minimum, conform with all required services. Proposed additional activities may be described in the Program Summary section. Please note, any additional activities will not be subject to scoring.
19	General, Section V, Completing the Proposal, page 16.	Will NYS DOH and HRI entertain a “coordinated proposal” submission from multiple laboratories/institutions that build on the collective infrastructure and expertise? This would entail: <ul style="list-style-type: none"> Each institution would submit a separate proposal, cross-referencing the other proposals. 	A coordinated proposal is an option. The individual proposals must demonstrate that all required qualifications are met and must describe the relationship and roles of the Applicant. Facilitating the movement and management of specimens and data must be carefully tracked to ensure integrity/quality are maintained. The NYS DOH will reimburse participating WGS laboratories at a rate of

		<ul style="list-style-type: none"> • NYS would be contracting separately with each institution for the respective Statement(s) of Work. • The institutions would establish Laboratory Service Agreements (LSAs) one-with-another, to achieve the collaborative goals of this effort. The budgeting for these LSAs would be reflected in the individual proposals. 	up to \$150 per sample. There are no alternate reimbursement opportunities for other activities.
20	Section IV, Administrative Requirements, Subsection I, page 10.	If selected for funding, is the sample contract included within the RFP negotiable (Section I. HRI Boilerplate Agreement)?	Provisions of the HRI Boilerplate Agreement may be discussed with the NYS DOH and HRI and may be subject to amendment.
21	Section IV, Administrative Requirements, Subsection I, page 10.	<p>The following exceptions are submitted in response to the HRI Boilerplate Agreement:</p> <ul style="list-style-type: none"> • We take exception to Article 5 of the HRI Boilerplate Agreement. • We take exception to Article 11 of the HRI Boilerplate Agreement. 	See response to question 20.