RFP Number WC- 2021-01

HEALTH RESEARCH, INC.

New York State Department of Health

Wadsworth Center/Division of Infectious Diseases
Laboratory of Viral Diseases

Request for Proposals

Building NYS Whole Genome Sequencing Capacity for SARS-CoV-2 Partnership

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KEY DATES

RFP Release Date:	**May 13, 2021**
Questions Due:	**May 20, 2021**
RFP Updates Posted:	**May 27, 2021**
Proposals Due:	**June 10, 2021**
Contact Name & Address:	**Deanna Laney, Assistant Director** New York State Department of Health Wadsworth Center, Biggs Laboratory Empire State Plaza Albany, NY 12237 COVID19.Sequencing.Labs@health.ny.gov

Table of Contents

I. Introduction

The Wadsworth Center (WC) is New York State's public health laboratory and serves a vital role in the New York State Department of Health's (NYS DOH) efforts to protect and promote the health of New Yorkers. The WC, 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, WC scientists use both classical and contemporary approaches to study biological and environmental 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; and train the next generation of scientists through undergraduate, graduate, postdoctoral and visiting scientist programs.

More information about the WC can be found at http://www.wadsworth.org.

With these capacities, the WC has played an essential role in NYS's response to COVID-19 (SARS-CoV-2). WC has maintained and supported a robust and multifaceted approach to maximize SARS-CoV-2 testing capacities both internally and through a network of external laboratories (hospitals, commercial laboratories, academic laboratories, and a variety of non-traditional entities). The WC performs high complexity diagnostic molecular and serology testing for SARS-CoV-2 as well as whole genome sequencing (WGS). The external laboratory network and non-traditional entities performing SARS-CoV-2 testing in NYS include nearly 2,000 laboratories reporting molecular results each day and over 100 laboratories reporting serology results daily to the NYS DOH. Additionally, several external laboratories are performing WGS of SARS-CoV-2 on NYS specimens. These laboratories include NYS Clinical Laboratory Evaluation Program (CLEP) permitted clinical laboratories and non-CLEP permitted research laboratories. The number of these laboratories is rising as efforts to understand the prevalence and spread of SARS-CoV-2 strains and sequence variants expand.

On March 10, 2021, the Centers for Medicare and Medicaid Services (CMS) announced that it will temporarily exercise enforcement discretion under Clinical Laboratory Improvement Amendments (CLIA) for SARS-CoV-2 genetic variant testing on identified specimens in which patient-specific results are reported to state or local public health departments only, allowing for sequencing data to be more fully examined and understood in the context of their impact on public health. Reporting of sequencing results to individual patients or their provider, however, is not allowed, unless the laboratory has a clinical laboratory permit in NYS and the assay has been approved by the US Food and Drug Administration or NYS CLEP.

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 NYS 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 research and public health programs and response. Clients include NYS DOH, 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's work aligns with the purposes and objectives of the NYS DOH and its associated institutions and agencies, engaged in health-related matters. HRI is an active partner with the ability to quickly execute contracts to assist its clients to carry out public health initiatives. More information can be

found at https://www.healthresearch.org/about-hri/missionvision-values/.

Establishing the purpose of this RFP

Beginning in March 2020, the WC performed WGS regularly on a subset of SARS-CoV-2 positive specimens as part of public health and molecular surveillance in NYS. WC uses WGS methodologies to produce full length sequences for broad surveillance of strains and sequence variants. In the advent of new variants emerging across the world, in late December 2020 the WC ramped up sequencing for SARS-CoV-2 from approximately 50 specimens every two weeks to over 90 specimens a day. To support this surveillance and to characterize the transmission dynamics of SARS-CoV-2 across the entire state, the WC partnered with more than 25 clinical facilities that submit SARS-CoV-2 positive specimens to WC for sequencing. In addition to geographic distribution, WC selectively analyzes specimens representing unique cases based on unusual disease manifestations, severity of illness, travel history, suspected therapy or vaccine evasion, and other scenarios of interest. WC also retrospectively sequenced positive samples from its own specimen archives from September through December 2020 to look for evidence of possible early entry of variants into NYS.

The New York City Department of Health and Mental Hygiene, medical centers, academic laboratories, and commercial laboratories conduct WGS providing population wide surveillance data of SARS-CoV-2 variants across the New York City (NYC) region. There are less WGS data for SARS-CoV-2 available in other regions of the state. Therefore, in order obtain more comprehensive sequence data across the entire State, NYS DOH is working to expand WGS capacities across the state (excluding NYC) to allow for broader surveillance.

With this RFP, the NYS DOH through HRI intends to subcontract with laboratories that have sequencing expertise, capacity, and access to SARS-CoV-2 positive specimens from upstate and Long Island counties (excluding the five counties/boroughs in NYC). While the Centers for Disease Control and Prevention (CDC) has contracted with several large commercial diagnostic laboratories and seven universities around the country to sequence a broad selection of samples from across the United States, this RFP offers an opportunity for clinical and academic laboratories to participate in and contribute to a more targeted sequencing effort in NYS. This RFP aims to provide WGS on approximately 10% of the SARS-CoV-2 positive specimens derived from upstate and Long Island NY.

The NYS DOH/HRI plans to enter into contractual agreements with the selected institutions/laboratories. The contractual agreements will be jointly managed by Grants Administration (GA) and WC and will extend for an 18-month duration or until the funding is exhausted.

II. Who May Apply

Applicants must have an established infrastructure for specimen receipt, processing, WGS, and bioinformatics analysis of the sequence data of human pathogens, including equipment, experience, and expertise in the processing of clinical specimens. Additionally, applicants must have established electronic networks, systems, and databases for recording and reporting all specimen and test associated information and data. They must be familiar and competent with accessing and uploading to public sequence databases. Further, applicants must have measures of quality metrics and quality assurance procedures in routine use, to assess and assure high operational standards, as well as established training and competency procedures for staff.

Specifically, applicant must meet the following minimum qualifications to apply:

1. Must be a CLEP permitted clinical, or non-CLEP permitted research laboratory operated by a degree conferring educational institution.

2. Demonstrated operational capacity in genomics with documented extensive experience performing WGS of pathogens.
3. Has established relevant training and competency procedures for staff.
4. Has established infrastructure for specimen receipt and processing of clinical specimens containing human pathogens.
5. Has access to SARS-CoV-2 positive specimens in a proposed multi-county catchment area. These positive SARS-CoV-2 specimens must be representative of the cases across the general population (not limited to a specific cohort or age group) and be from a broad region(s) of upstate or Long Island NY (excluding the five counties/boroughs of NYC).
6. Has established electronic networks, systems, and databases for recording and reporting all specimen and test associated information and data.
7. Possesses bioinformatics expertise in Next Generation Sequencing (NGS) data analysis of pathogens.
8. Maintains infrastructure to upload sequence data to the Global Initiative on Sharing All Influenza Data (GISAID) at minimum every two weeks.

Applicants that meet one or more of the following Preferred Eligibility Requirements, may receive additional points as proposals are scored.

1. Demonstrated experience with WGS for SARS-CoV-2.
2. Maintains infrastructure/capacity to upload sequence data to the National Center for Biotechnology Information (NCBI) and Sequence Read Archive (SRA).

III. Project Narrative/ Work Plan Outcomes

Participating laboratories will perform WGS of SARS-CoV-2. The WC will provide guidance for the performance of WGS and data interpretation to ensure comparability of the data across the partner laboratories. This guidance will consider CDC strategies. The laboratories will conform with the WC guidance for the purposes of the testing, data analysis, and reporting for the work performed under this contract.

Analysis will be performed on SARS-CoV-2 positive specimens from the general population in upstate and Long Island NY counties. Counties of the state targeted include all except the five counties comprising NYC. Applicants must identify a catchment area comprised of multiple counties for which they will provide population surveillance. Applicants must *aim* to perform WGS on a minimum of 10% of the SARS-CoV-2 positive specimens in their catchment area. County-level SARS-CoV-2 positive case data are available at https://forward.ny.gov/percentage-positive-results-county-dashboard and https://health.data.ny.gov and participating laboratories must remain aware of the positivity rate at the time of sequencing and adjust their testing quantity accordingly. In addition to surveillance of the general population, the participating laboratories may be requested to perform WGS on specimens from unique cases including unusual disease manifestations, severity of illness, travel history, suspected therapy or vaccine evasion, and other scenarios of clinical and/or public health interest.

The NYS DOH will reimburse participating laboratories for the work completed at a rate of up to $150 per sample, which is intended to cover the cost of the resources necessary to perform this testing, including labor and reagents for receiving, accessioning, extraction, cDNA generation, amplification, library preparation, sequencing, bioinformatic analysis, reporting, and database upload. The duration of this contract is up to 18 months or until the funding is exhausted.

The participating laboratories will provide Status Updates biweekly (every two weeks) and Progress Reports every 6 months and at the end of the contract period. Status Updates will capture progress

during the reporting period including the number of SARS-CoV-2 specimens sequenced, the number of results uploaded to GISAID, the percentage of SARS-CoV-2 positive samples sequenced in relation to the number of positive cases at a county level, and other details further described in Attachment 4. Progress Reports will provide cumulative summary data and information. Participating laboratories are required to perform biweekly data uploads to GISAID of their sequences and participate on monthly consortium calls. Participating laboratories shall aim to upload all sequence results to GISAID; uploads for a reporting period containing less than 90% of test results must be explained in the Status Updates. Further, GISAID uploads must include complete metadata such as age, sex, and county of origin in the location field. In addition to GISAID, uploads to NCBI and SRA are strongly encouraged and may become required. Additional results reporting may be required.

Any significant issues that cause, or are predicted to cause, delays to processing, testing, or reporting in a given two-week period must be promptly reported to the WC. Following such an event, the contract laboratory will submit an Adverse Event Report to WC.

IV. Administrative Requirements

A. Issuing Agency

This RFP is issued by the NYS DOH WC's Division of Infectious Diseases, Laboratory of Viral Diseases and HRI with funding provided by the Centers for Disease Control and Prevention's, Epidemiology and Laboratory Capacity for Prevention and Control of Emerging Infectious Diseases (*ELC) Enhancing Detection Expansion* supplement. HRI/NYS DOH are responsible for the requirements specified herein and for the evaluation of all proposals.

B. Question and Answer Phase:

All substantive questions must be submitted in writing to:

Deanna Laney, Assistant Director
NYS Department of Health, Wadsworth Center
Room E260, Biggs Laboratory
Empire State Plaza
Albany, NY 12237
COVID19.Sequencing.Labs@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.

Questions of technical nature can be addressed in writing or via telephone by calling Deanna Laney at (518) 474-7592. **Questions are of technical nature if they are limited to how to prepare your proposal (e.g., formatting) rather than relating to the substance of the proposal.**

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

This RFP has been posted on HRI's public website at:

http://www.healthresearch.org/funding-opportunities. Questions and answers, as well as any updates and/or modifications, will also be posted on HRI's website. All such updates will be posted by the date identified on the cover sheet of this RFP.

If prospective bidders would like to receive notification when updates/modifications are posted (including responses to written questions), please complete and submit a letter of interest (see Attachment 1). Prospective bidders may also use the letter of interest to request actual (hard copy) documents containing updated information.

Submission of a letter of interest is NOT a requirement for submitting a proposal.

C. Bidder Conference

A Bidder Conference WILL NOT **be held for this project.**

D. How to file a proposal

Proposals must be **received** at the following address by 6:00 PM on June 10, 2021. Late proposals will NOT be accepted.

Attn: Deanna Laney, Assistant Director
NYS Department of Health, Wadsworth Center
Room E260, Biggs Laboratory
Empire State Plaza
Albany, NY 12237

Bidders shall submit one (1) original, signed proposal and five (5) copies. Proposal packages should be clearly labeled with the name and number of the RFP as listed on the cover of this RFP document. **Proposals WILL also be accepted via e-mail at:**

COVID19.Sequencing.Labs@health.ny.gov

*It is the bidder's responsibility to see that proposals are delivered to the address above prior to the date and time specified above. Late proposals due to documentable delay by the carrier may be considered at HRI's discretion.

E. THE DEPARTMENT OF HEALTH & HRI RESERVE THE RIGHT TO

1. Reject any or all proposals received in response to this RFP.

2. Withdraw the RFP at any time, at HRI's sole discretion.

3. Make an award under the RFP in whole or in part.

4. Disqualify any bidder 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 a bidder's qualifications, experience, ability or financial standing, and any material or information submitted by the bidder in response to the agency's request for clarifying information in the course of evaluation and/or selection under the RFP.

7. Prior to application 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 bidders 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 bidder, should HRI be unsuccessful in negotiating with the selected bidder.

13. Utilize any and all ideas submitted with the proposals received.

14. Unless otherwise specified in the RFP, every offer is firm and not revocable for a period of 60 days from the bid opening.

15. Waive or modify minor irregularities in proposals received after prior notification to the bidder.

16. 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 offeror's proposal and/or to determine an offeror's compliance with the requirements of the RFP.

17. Negotiate with successful bidders within the scope of the RFP in the best interests of HRI.

18. Eliminate any mandatory, non-material specifications that cannot be complied with by all bidders.

19. 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 Health Research, Inc.

It is expected that contracts resulting from this RFP will have an 18-month contract duration with the possibility of renewals if additional funding becomes available. Renewals are dependent upon satisfactory performance and continued funding.

G. Payment & Reporting Requirements

The contractor shall submit invoices and required reports as described below:

Invoices containing the number of specimens processed in the month prior must be submitted MONTHLY to Grants@health.ny.gov with a copy to COVID19.Sequencing.Labs@health.ny.gov.

Status Updates must be submitted BIWEEKLY (every two weeks) by Tuesday to reflect the previous two weeks (Monday to Sunday) testing and reporting. See Attachment 4 for a list of the information to be reported in the Status Updates. A template will be provided by the NYS DOH to the contract laboratories. Status Updates will be sent via email to COVID19.Sequencing.Labs@health.ny.gov

Uploads to GISAID must be conducted BIWEEKLY (every two weeks). Uploads to NCBI and SRA are strongly encouraged, at a frequency to be determined.

Progress Reports must be submitted every 6 MONTHS and one at the completion of the contract (18 months) providing a summary of the work performed and cumulative data and information. A template will be provided to the contract laboratories. Progress Reports will be sent via email to COVID19.Sequencing.Labs@health.ny.gov.

Adverse Event Reports will be sent, AS NEEDED, following any significant issues to processing, testing, or reporting via email to COVID19.Sequencing.Labs@health.ny.gov. See Attachment 5 for the Adverse Event Report template.

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

H. General Specifications

1. By signing the "Proposal Form" each bidder attests to its express authority to sign on behalf of the bidder.

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. Contractor will possess, at no cost to HRI or the state, all qualifications, licenses, permits, expertise, facilities and support services for information technology, data analysis, data transfer, and upload.

4. Submission of a proposal indicates the bidder'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.

5. A bidder may be disqualified from receiving awards if such bidder 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.

6. Provisions Upon Default

    a. The services to be performed by the Bidder 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 Bidder, 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 Bidder.

7. Bidder must maintain an active registration in the System for Award Management (SAM) at SAM.gov, have no exclusions or delinquent federal debt.

I. HRI Boilerplate Agreement

Selected contractor will be expected to sign the below Agreement.

THIS AGREEMENT, made as of «Start_Date» (the “Effective Date”), by and between **HEALTH RESEARCH, INC.**, a not for profit corporation organized and existing under the laws of the State of New York, with principal offices located at Riverview Center, 150 Broadway, Ste. 560, Menands, NY 12204, hereinafter referred to as **HRI**, and **«CONSULTANT_NAME»**, located at «Address_One», «Address_Two»«City», «STATE», «Zip», herein after referred to as the **CONSULTANT**.

WITNESSETH

WHEREAS, HRI has been awarded a grant from «Sponsor_Name» for the conduct of a project entitled "«Project_Title»"; and,

WHEREAS, funding for the project, in whole or in part, is provided under a federal government grant or contract; and,

WHEREAS, HRI desires the Consultant's performance of certain services for HRI in connection with such project; and,

WHEREAS, Consultant has represented to HRI that "he/she/it" is competent, willing and able to perform such services for HRI.

NOW THEREFORE, in consideration of the promises, mutual covenants, and agreements contained herein, it is mutually agreed by and between the respective parties as follows:

1. Consultant agrees to perform, as an independent contractor and not as an employee or agent of HRI, all the services set forth in Exhibit "A", appended hereto and made a part hereof, to the satisfaction of HRI's Principal Investigator, «PI_Name».

2. The Agreement shall be effective and allowable costs may be incurred by the Consultant from the Effective Date and shall continue until «End_Date» (the “Term”) unless terminated sooner as hereinafter provided or extended by written agreement of the parties.

3. In full and complete consideration of Consultant's performance hereunder, HRI agrees to compensate Consultant pursuant to the breakdown in Exhibit "A" attached. Final invoices are due within 60 days of the termination date of this Agreement. Requests received after this 60-day period may not be honored. Any reimbursement payable hereunder by HRI to the Consultant shall be subject to retroactive reductions and/or repayment for amounts included therein which are identified by HRI, on the basis of any review or audit, to not constitute an allowable cost or charge hereunder.

4. The Scope of Work and Budget in Exhibit "A" may be modified as conditions warrant by mutual agreement between HRI and Consultant, and confirmed in writing. In no event shall the total consideration under this Agreement exceed Total Contract Amount Typed Out Dollars ($«Total_Contract_Amt_In_Numbers»).

5. Consultant acknowledges and agrees that all work products, deliverables, designs, writings, inventions, discoveries, and related materials, (collectively “Works”) made, produced or delivered by Consultant in the performance of its obligations hereunder will be owned exclusively by HRI. All copyrightable Works are "works made for hire". Consultant will assign, and hereby assigns and transfers, to HRI all intellectual property rights in and to Works, including without limitation, copyrights, patent rights, trademark rights, and trade secret rights. Consultant further agrees that "he/she/it" shall not claim or assert any proprietary interest in any of the data or materials required to be produced or delivered by Consultant in the performance of its obligation hereunder. Consultant warrants that all Works shall be original except for such portion from copyrighted works as may be included with Consultant’s advance permission of the copyright owner(s) thereof, that it shall contain no libelous or unlawful statements or materials, and will not infringe upon any copyright, trademark or patent, statutory or other proprietary rights of others. Consultant further agrees that "he/she/it" will not publish, permit to be published, or distribute for public consumption, any information, oral or written, concerning the results or conclusions made pursuant to this Agreement without the prior written consent of HRI.

6. Neither party shall use the name of the other or any adaptation, abbreviation or derivative of any of them, whether oral or written, without the prior written permission of the other party. For the purposes of this paragraph "party" on the part of HRI shall include the State of New York and the NYS Department of Health.

7. It is understood and agreed that the services to be rendered by Consultant are unique and that Consultant shall not assign, transfer, subcontract or otherwise dispose of its rights or duties hereunder, in whole or in part, to any other person, firm or corporation, without the advance written consent of HRI.

8. The nature of the relationship which the Consultant shall have to HRI pursuant to this Agreement shall be that of an independent contractor. Under no circumstance shall the Consultant be considered an employee or agent of HRI. This Agreement shall not be construed to contain any authority, either expressed or implied, enabling the Consultant to incur any expense or perform any act on behalf of HRI.

9. Consultant is solely responsible for complying with all applicable laws, including but not limited to those specified in Appendix “A”, and obtaining, at Consultant’s sole expense, any and all licenses, permits, or authorizations necessary to perform services hereunder.

10. This Agreement shall be void and no force and effect unless Consultant shall provide and maintain coverage during the life of this Agreement for the benefit of such employees as are required to be covered by the provisions of Workers’ Compensation Law.

11. Unless otherwise agreed by HRI, Consultant shall maintain, or cause to be maintained, during the Term of this Agreement, insurance or self-insurance equivalents of the following types and amounts: a) Commercial General Liability (CGL) with limits of insurance of not less than $1,000,000 each occurrence and $2,000,000 annual aggregate: b) HRI and the People of the State of New York shall be included as Additional Insureds on the Consultant’s CGL, using ISO Additional Insured Endorsement CG 20 10 11 85 or an endorsement providing equivalent coverage to the Additional Insureds. The CGL insurance for the Additional Insureds shall be as broad as the coverage provided for the Named Insured Consultant. It shall apply as primary and non-contributing insurance before any insurance maintained by the Additional Insureds; c) other such insurance as may be specified by HRI, depending on the project and services provided by Consultant.

12. Consultant shall establish and maintain complete and accurate books, records, documents, accounts and other evidence directly pertinent to performance of the services under this Agreement (collectively, “Records”). The Records must be kept for the balance of the calendar year in which they are created and for six years thereafter. HRI shall have reasonable access to such Records as necessary for the purposes of inspection, audit, and copying. Records shall be maintained as Confidential Information and protected from public disclosure.

13. This Agreement, including all applicable attachments and appendices thereto, represents the entire Agreement and understanding of the parties hereto and no prior writings, conversations or representations of any nature shall be deemed to vary the provisions hereof. This Agreement may not be amended in any way except in writing, duly executed by both parties hereto.

14. HRI may terminate this Agreement with or without cause at any time by giving advance notice, when, in its sole discretion, HRI determines that it is in the best interests of HRI to do so, or as directed by the project sponsor. Such termination shall not affect any commitments which, in the judgment of HRI, have become legally binding prior to the effective date of termination. Upon termination of the Agreement by either party for any reason, Consultant shall immediately turn over to HRI any works in progress, materials, and deliverables (whether completed or not) related to the services performed up to the date of termination. It is understood and agreed, however, that in the event that Consultant is in default upon any of its obligations, hereunder, at the time of such termination, such right of termination on the part of HRI shall expressly be in addition to any other rights or remedies which HRI may have against Consultant by reason of such default.

15. Consultant acknowledges and agrees that, during the course of performing services for HRI, it may receive information of a confidential nature, whether marked or unmarked (“Confidential Information”). Consultant agrees to protect such Confidential Information with the same degree of care it uses to protect its own confidential information of similar nature and importance, but with no less than reasonable care. Consultant will not use Confidential Information for any purpose other than to facilitate the provision of services under this Agreement, and Consultant will not disclose Confidential Information to any third party without HRI’s advance written consent.

16. Consultant represents and warrants that: a) it has the full right and authority to enter into and perform under this Agreement; b) it will perform the services set forth in Exhibit "A" in a workmanlike manner consistent with applicable industry practices; c) the services, work products, and deliverables provided by Consultant will conform to the specifications in Exhibit "A"; d) there is no pending or threatened claim or litigation that would have a material adverse impact on its ability to perform as required by this Agreement.

17. Consultant shall have no interest, financial or otherwise, direct or indirect, or engage in any business, transaction, or professional activity, that may create a conflict with the proper discharge of Consultant’s duties under this Agreement. In the event any actual or potential conflict arises, Consultant agrees to notify HRI in writing within ten (10) days to allow HRI to evaluate any potential impact on Consultant’s performance under this Agreement.

18. To the fullest extent permitted by law, Consultant shall indemnify, hold harmless and defend HRI, its agents, employees, officers, board members, the New York State Department of Health, and the People of the State of New York against all claims, damages, losses or expenses including but not limited to attorneys’ fees arising out of or resulting from the performance of the agreement, provided any such claim, damage, loss or expense arises out of, or in connection with, any act or omission by Consultant, or anyone directly or indirectly employed or contracted by Consultant, in the performance of services under this Agreement, and such acts or omissions (i) constitute negligence, willful misconduct, or fraud; (ii) are attributable to bodily injury, sickness, disease or death, or to injury to or destruction of tangible property, including loss of use resulting there from; (iii) cause the breach of any confidentiality obligations set forth herein; (iv) relate to any claim for compensation and payment by any employee or agent of Consultant; (v) result in intellectual property infringement or misappropriation by Consultant, its employees, agents, or subcontractors; or (vi) are violations of regulatory or statutory provisions of the New York State Labor Law, OSHA or other governing rule or applicable law. The obligation of the Consultant to indemnify any party under this paragraph shall not be limited in any manner by any limitation of the amount of insurance coverage or benefits including workers’ compensation or other employee benefit acts provided by the Consultant.

19. Should any provision of this Agreement be proven to be invalid or legally ineffective, the overall validity of this Agreement shall not be affected. Unless the parties agree on an amended provision, the invalid provision shall be deemed to be replaced by a valid provision accomplishing as far as possible the purpose and intent of the parties at the date of the Agreement.

20. The failure of HRI to assert a right hereunder or to insist on compliance with any term or condition of this Agreement shall not constitute a waiver of that right of HRI, or other rights of HRI under the Agreement, or excuse a subsequent failure to perform any such term or condition by Consultant.

21. This Agreement shall be governed and construed in accordance with the laws of the State of New York. The jurisdictional venue for any legal proceedings involving this Agreement shall be in the State of New York. Disputes involving this Agreement may not be submitted to binding arbitration.

22. In addition to the methods of process allowed by the State Civil Practice Law & Rules (CPLR), in any litigation arising under or with respect to this Agreement, Consultant hereby consents to the service of process upon it by registered or certified mail, return receipt requested, and will promptly notify HRI in writing in the event there is any change of address to which service of process can be made.

23. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Delivery of an executed signature page to the Agreement by facsimile transmission or PDF shall be as effective as delivery of a manually signed counterpart.

Consultant agrees to abide by the terms and conditions of Appendix "A" attached hereto and made a part hereof, including the provisions required for federally funded projects, if applicable.

HEALTH RESEARCH, INC.
APPENDIX A to AGREEMENT WITH ENTITY

The parties to the attached Agreement further agree to be bound by the following terms, which are hereby made a part of said Agreement:

1. During the performance of the Agreement, the Consultant agrees as follows:

   (a) Equal Opportunity and Non-Discrimination - Consultant acknowledges and agrees, whether or not required by Article 15 of the New York State Executive Law (also known as the Human Rights Law) or any other State or Federal statutory or constitutional non-discrimination or civil rights provisions, including but not limited to the American Disabilities Act, that Consultant will not discriminate against any employee or applicant for employment because of race, color, creed, religion, sex, sexual orientation, gender identity, national origin, age, disability, pregnancy-related condition, military or veteran status, genetic predisposition or carrier status, marital or familial status, domestic violence victim status, individual's relationship or association with a member of a protected category or any other basis protected by state and federal law. Furthermore, Consultant agrees that neither it nor its authorized subcontractors, if any, shall, by reason of race, color, creed, religion, sex, sexual orientation, gender identity, national origin, age, disability, pregnancy-related condition, military or veteran status, genetic predisposition or carrier status, marital or familial status, domestic violence victim status, individual's relationship or association with a member of a protected category or any other basis protected by applicable state and federal law: (a) discriminate in hiring against any New York State citizen who is qualified and available to perform the work; or (b) discriminate against or intimidate any employee hired for the performance of work under this Agreement. Consultant is subject to Section 220-e or Section 239 of the New York State Labor Law for work performed under this Agreement. Pursuant thereto, Consultant is subject to fines of $50.00 per person per day for any violation of this provision, which may be deducted from any amounts payable under this Agreement, as well as possible termination of this Agreement and forfeiture of all moneys due hereunder for a second or subsequent violation.

   (b) This contractor and subcontractor shall abide by the requirements of 41 CFR 60-1.4(a) which is hereby incorporated herein.

   This contractor and subcontractor shall abide by the requirements of 41 CFR 60-741.5(a). This regulation prohibits discrimination against qualified individuals on the basis of disability, and requires affirmative action by covered prime contractors and subcontractors to employ and advance in employment qualified individuals with disabilities.

   This contractor and subcontractor shall abide by the requirements of 41 CFR 60-300.5(a). This regulation prohibits discrimination against qualified protected veterans, and requires affirmative action by covered prime contractors and subcontractors to employ and advance in employment qualified protected veterans.

(c) System for Award Management (SAM) - Consultant is required to register with SAM.gov and maintain active status as stated in 2 CFR Subtitle A, Chapter 1, and Part 25 of Code of Federal Regulations. **Consultant** must maintain the accuracy/currency of the information in SAM at all times during which your entity has an active agreement with HRI. Additionally, your entity is required to review and update the information at least annually after the initial registration, and more frequently if required by changes in your information.

2. Assurances Required by DHHS--HHS (Where Applicable)

(a) Human Subjects, Derived Materials or Data

The Consultant and HRI both agree to abide by DHHS regulations concerning Human Subjects. The DHHS regulation, 45 CFR 46, provides a systematic means, based on established ethical principles, protecting the rights and welfare of individuals who may be exposed to the possibility of physical, psychological or social injury while they are participating as subjects in research, development or related activities. The regulation extends to the human fetus (either in utero or ex utero), the dead, organs, tissues, and body fluids, and graphic, written or recorded information derived from human sources.

The DHHS regulation requires institutional assurances, including the implementation of procedures for review, and the assignment of responsibilities for adequately protecting the rights and welfare of human subjects. Safeguarding these rights and welfare is, by DHHS policy, primarily the responsibility of the grantee. The Consultant is responsible for ensuring that the activity described or covered by this Agreement, and additional information relating to human subjects, derived materials or data are annually reviewed and approved by the Institutional Review Board of the Consultant. The Consultant and HRI agree to complete a HHS 596 form on an annual basis.

(b) Laboratory Animals

The Consultant agrees to abide by HHS policy requiring that laboratory animals not suffer unnecessary discomfort, pain or injury. The Consultant must assure HHS, in writing that it is committed to following the standards established by the Animal Welfare Acts and by the documents entitled “Principles for Use of Animals “and” Guide for the Care and Use of Laboratory Animals."

(c) Recombinant DNA

The Consultant agrees to abide by the current HHS Guidelines for Research involving Recombinant DNA Molecules. All research involving recombinant DNA techniques that is supported by the Public Health Service must meet the requirements of these Guidelines, which were developed in response to the concerns of the scientific and lay communities about the possible effects of recombinant DNA research. Their purpose is to specify practices for the construction and handling of recombinant DNA molecules and organisms or viruses containing recombinant DNA. As defined by the Guidelines, "recombinant DNA" corresponds to: (1) molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell; or (2) DNA molecules that result from the replication of a molecule described in (1).

Several types of studies involving recombinant DNA are exempt from the Guidelines while others are prohibited by the Guidelines. For the remainder, the Consultant must establish and implement policies that provide for the safe conduct of the research in full conformity with the Guidelines. This responsibility includes establishing an institutional biosafety committee to review all recombinant DNA research to be conducted at or sponsored by the Consultant and to approve those projects that are in conformity with the Guidelines. For each approved project, a valid Memorandum of Understanding and Agreement (MUA) shall be prepared for submission when solicited by an appropriate HHS staff member. The MUA is considered approved after review and acceptance by ORDA and by the Consultant.

(d) Promoting Objectivity in Research

Neither Consultant nor anyone working on its behalf shall have any interest, financial or otherwise, direct or indirect, or engage in any business, transaction, or professional activity that may create a conflict, or the appearance of a conflict, with the proper discharge of Consultant’s duties under this Agreement or the conflict of interest policy of any agency providing federal funding under this Agreement. In the event any actual or potential conflict arises, Consultant agrees (i) to notify HRI in writing within ten (10) days to allow HRI to evaluate any potential or actual conflict, and, (ii) if required, eliminate the conflict or put in place an acceptable conflict management plan. Consultant agrees to comply with the DHHS/HHS regulatory requirements on Responsibility of Applicants for Promoting Objectivity in Research and financial conflicts of interest set forth in 42 CFR Part 50 Subpart F, as may be amended from time to time. Failure to disclose conflicts or provide information related thereto to HRI may be cause for termination of the Agreement

(e) Additional Assurances

Should any additional DHHS-HHS regulations be promulgated that are applicable to this Agreement, the Consultant and HRI will review and agree to include them as part of this Agreement.

(f) National Labor Relations Act (Executive Order 13496)
Contractors that are not exempt from the National Labor Relations Act and have contracts, subcontracts or purchase orders subject to EO 13496 must satisfy the requirements of that Executive Order and its implementing regulations at 29 CFR Part 471 to be in compliance with the law.

The following provisions 3-6 are applicable to federally funded projects:

3. Clean Air Act and the Federal Water Pollution Control Act Compliance - If this Agreement is in excess of $150,000, Consultant agrees to comply and to require that all subcontractors comply, where applicable, with all applicable standards, orders or regulations issued pursuant to the Clean Air Act (42 U.S.C. § 7401-7671q.) and the Federal Water Pollution Control Act as amended (33 U.S.C. §1251-1387). Violations must be reported to the Federal awarding agency and the Regional Office of the Environmental Protection Agency (EPA).

4. Notice as Required Under Public Law 103-333 - The Consultant is hereby notified of the following statement made by the Congress at Section 507(a) of Public Law 103-333 (The DHHS Appropriations Act, 1995, hereinafter the "Act"): It is the sense of the Congress that, to the greatest extent practicable, all equipment and products purchased with funds made available in this Act should be American-made.

5. Required Federal Certifications -Acceptance of this Agreement by Consultant constitutes certification by the Consultant of all of the following:

   (a) The Consultant is not presently debarred, suspended, proposed for debarment, declared ineligible or voluntarily excluded from covered transactions by any Federal department or agency.

   (b) The Consultant is not delinquent on any Federal debt.

   (c) The Consultant will comply with the Byrd Anti-Lobbying Amendment (31 U.S.C. § 1352) requiring for Agreements of $100,000 or more, that Consultant (i).will not and has not used Federal appropriated funds to pay any person or organization for influencing or attempting to influence an officer or employee of any agency, a member of Congress, officer or employee of Congress, or an employee of a member of Congress in connection with obtaining any Federal contract, grant or any other award covered by 31 U.S.C. § 1352, and (ii) will disclose any lobbying with non-Federal funds that takes place in connection with obtaining any Federal award. Such disclosures are forwarded from tier to tier up to the non-Federal award.

   (d) The Consultant shall comply with the requirements of the Pro-Children Act of 1994 and shall not allow smoking within any portion of any indoor facility used for the provision of health, day care, early childhood development, education or library services to children under the age of eighteen (18) if the services are funded by a federal program, as this Agreement is, or if the services are provided in indoor facilities that are constructed, operated or maintained with such federal funds.

   (e) The Consultant has established administrative policies regarding Scientific Misconduct as required by the Final Rule 42 CFR Part 93, Subpart A as published at the 54 Federal Register 32446, August 8, 1989.

   (f) The Consultant maintains a drug free workplace in compliance with the Drug Free Workplace Act of 1988 as implemented in 45 CFR Part 76.

   (g) If the Project Sponsor is either an agency of the Public Health Service or the National Science Foundation, the Consultant is in compliance with the rules governing Objectivity in Research as published in 60 Federal Register July 11, 1995.

6. Whistleblower Policy - Congress has enacted whistleblower protection statue 41 U.S.C. 4712, which applies to all employees working for contractors, grantees, subcontractors, and sub-grantees on federal grants and contracts. This program requires all grantees, sub-grantees and subcontractors to: inform their employees working on any federally funded award they are subject to the whistleblower rights and remedies of the program; inform their employee in writing of employee whistleblower protections under 41 U.S.C. 4712 in the predominant native language of the workforce; and Contractors and grantees will include such requirements in any agreement made with a subcontractor or sub-grantee.

The statue (41 U.S.C. 4712) states that an "employee of a contractor, subcontractor, grantee [or sub-grantee] may not be discharged, demoted, or otherwise discriminated against as a reprisal for "whistleblowing". In addition, whistleblower protections cannot be waived by any agreement, policy, form, or condition of employment.

Whistleblowing is defined as making a disclosure "that the employee reasonably believes is evidence of any of the following: gross mismanagement of a federal contract or grant; a gross waste of federal funds; an abuse of authority relating to a federal contract or grant; a substantial and specific danger to public health or safety; or a violation of law, rule, or regulation related to a federal contract or grant (including the competition for, or negotiation of, a contract or grant). To qualify under the statute, the employee's disclosure must be made to: a Member of Congress or a representative of a Congressional committee; or an Inspector General; or the Government Accountability Office; or a Federal employee responsible for contract or grant oversight or management at the relevant agency; or an authorized official of the Department of Justice or other law enforcement agency; or a court or grand jury; a management official or other employee of the contractor, subcontractor, grantee or sub-grantee who has the responsibility to investigate, discover or address misconduct.

The Consultant shall require that the language of all of the above certifications will be included in the award documents for all subawards under this Agreement (including subcontracts, subgrants, and contracts under grants, loans and cooperative agreements) and that all subrecipients shall certify and disclose accordingly.

The Consultant agrees to notify HRI immediately if there is a change in its status relating to any of the above certifications.

V. Completing the Proposal

A. Proposal Content

1. Cover Page

The cover page should include the title of the proposal, the institution/laboratory name, mailing address and telephone number, and the technical and administrative contacts (name, address, phone, and e-mail address). See Attachment 3.

2. Program Summary (60 points, with 8 bonus points)

This section must describe the following:

- Current laboratory type (i.e., CLEP permitted clinical or non-CLEP permitted research laboratory).
- Experience performing WGS of pathogens including the number of months or years and information concerning throughput or capacity (8 points).
- Established electronic networks, systems, and databases for recording and reporting all specimens and test associated information and data (7 points).
- Bioinformatics expertise in Next Generation Sequencing (NGS) data analysis of pathogens (5 points).
- Experience and infrastructure to upload sequence data to GISAID (5 points).
- How the testing experience, infrastructure, equipment, and expertise will be utilized to perform WGS of SARS-CoV-2 for this contract (5 points). **Describe the proposed plan to meet the objectives of the RFP (i.e., provide broad population surveillance in an upstate and/or Long Island region or regions of the State) including maximum throughput based on capacity, proposed throughput (aim for a minimum of 10% of the SARS-CoV-2 positive specimens in your catchment area), and plans for reporting to the NYS DOH and sequence upload to GISAID** (15 points). **Describe quality assurance procedures in routine use, to assess and assure high operational standards** (5 points). **Describe the budget (costs associated with labor and reagents for receiving, accessioning, extraction, cDNA generation, amplification, library preparation, sequencing, bioinformatic analysis, reporting, and database upload) and based on that, generate a**

cost per sample and identify the cost per sample sought for reimbursement (10 points). (Note: The reimbursement rate will not exceed $150 per sample. The budget description should acknowledge any internal investments to support this work should the costs exceed the reimbursed amount.)

For additional bonus points (8 points), describe:

- Experience performing WGS of SARS-CoV-2 including duration and throughput or capacity. Describe the maximum cycle threshold (CT) of specimens successfully sequenced (5 bonus points).
- Experience and infrastructure to upload sequence data to NCBI and SRA (3 bonus points).

3. Statement of Need (25 points)

This section must describe the following:

- Infrastructure for obtaining SARS-CoV-2 specimens including who collects the specimens, quantity of specimens received by the laboratory per week, and percentage of positive specimens with a CT deemed appropriate by the laboratory for WGS. Describe both the current infrastructure and, if necessary, any proposed modifications planned to meet the objectives of the RFP (10 points).
- The catchment area including a list of the counties and their population and number of current cases (8 points).
- How the specimens received or proposed for receipt represent the population in the respective catchment area and how this may be amended over time to ensure it remains representative of the general population (7 points).

4. Bidder Organization (5 points)

Describe the institution's/laboratory's mission and services (2 points). Describe how the proposed plan aligns with and supports the mission and services (3 points).

5. Program Activities (10 points)

Describe the organizational structure of the proposed program, including essential staff and their qualifications (Licensure, Certification, Curricula Vitae) (3 points). Describe the established relevant training and competency procedures for staff (5 points). Describe the roles of the individuals that will complete the proposed plan (2 points).

B. Proposal Format

ALL PROPOSALS MUST CONFORM TO THE FORMAT PRESCRIBED BELOW. POINTS WILL BE DEDUCTED FROM PROPOSALS WHICH DEVIATE FROM THE PRESCRIBED FORMAT.

Proposals MUST NOT exceed *12 SINGLE, DOUBLE* -spaced typed pages (not including the cover page and any attachments), using Arial font, size 11 or 12. The value assigned to each section is an indication of the relative weight that will be given when scoring your proposal.

1. Program Summary (6 pages or less) (Maximum Score: 60 points; 8 bonus points)

2. Statement of Need (3 pages) (Maximum Score: 25 points)

3. Bidder Organization (1 page) (Maximum Score: 5 points)

4. Program Activities (2 pages) (Maximum Score: 10 points)

C. Review Process

Proposals meeting the guidelines set forth above will be reviewed and evaluated competitively by HRI and the NYS DOH WC's Division of Infectious Diseases, Laboratory of Viral Diseases.

A team of individuals at the WC will review each proposal received and score them consistent with Section V. A. above. The NYS DOH's goal is to partner with institutions/laboratories that collectively provide representative coverage across upstate and Long Island NY. If proposals are received from two or more entities offering the same population/regional coverage, the entity with the highest score will be considered. If an entity is qualified and provides coverage of a population/region that no other applicant can provide, this applicant may be considered even if their proposal's score is lower than another applicant's.

Proposals failing to provide all response requirements or failing to follow the prescribed format may be removed from consideration or points may be deducted.

In the event of a tied score, a combination of variables will be considered including population represented, maximum/proposed throughput, and experience performing WGS on SARS-CoV-2 specimens.

If changes in funding amounts are necessary for this initiative, funding will be modified and awarded in the same manner as outlined in the award process described above (fee for service reimbursement).

VI. Attachments

Attachment 1: Letter of Interest Format
Attachment 2: Proposal Checklist
Attachment 3: Proposal Cover Sheet
Attachment 4: Status Update Information
Attachment 5: Adverse Event Report

Sample

Letter of Interest
or
Letter to Receive RFP Updates and Modifications

NYS DOH Contact
NYS DOH Address

Re: RFP #
RFP Title

Dear _____:

This letter is to indicate our interest in the above Request for Proposals (RFP) and to request: *(please check one)*

- ☐ That our organization is notified, via the e-mail address below, when any updates, official responses to questions, or amendments to the RFP are posted on HRI's website: http://www.healthresearch.org/funding-opportunities/.

  E-mail address: _____

- ☐ That our organization is unable or prefers not to use HRI's website and requests the actual documents containing any updates, official responses to questions, or amendments to the RFP be mailed to the address below:

  _____
  _____
  _____

Sincerely,

Proposal Checklist

1. Cover Page

- ☐ The cover page should include the title of the proposal, the institution/laboratory name, mailing address and telephone number, and the director, technical and administrative contacts (name, address, phone, and e-mail address). (Attachment 3 contains a template).

2. Program Summary (60 points, with 8 bonus points)

Description of the following:

- ☐ Current laboratory type (i.e., CLEP permitted clinical, or non-CLEP permitted research laboratory operated by a degree conferring educational institution).
- ☐ Experience performing WGS of pathogens including the number of months or years and information concerning throughput or capacity (8 points).
- ☐ Established electronic networks, systems, and databases for recording and reporting all specimens and test associated information and data (7 points).
- ☐ Bioinformatics expertise in Next Generation Sequencing (NGS) data analysis of pathogens (5 points).
- ☐ Experience and infrastructure to upload sequence data to GISAID (5 points).
- ☐ How the testing experience, infrastructure, equipment, and expertise will be utilized to perform WGS of SARS-CoV-2 for this contract (5 points). In addition, describe the proposed plan addressing the areas below:
  - **Describe the proposed plan to meet the objectives of the RFP (i.e., provide broad population surveillance in an upstate and/or Long Island region or regions of the State) including maximum throughput based on capacity, proposed throughput (aim for a minimum of 10% of the SARS-CoV-2 positive specimens in your catchment area), and plans for reporting to the NYS DOH and sequence upload to GISAID** (15 points).
  - **Describe quality assurance procedures in routine use, to assess and assure high operational standards** (5 points).
  - **Describe the budget (costs associated with labor and reagents for receiving, accessioning, extraction, cDNA generation, amplification, library preparation, sequencing, bioinformatic analysis, reporting, and database upload) and based on that, generate a cost per sample and identify the cost per sample sought for reimbursement** (10 points). (Note: The reimbursement rate will not exceed $150 per sample. The budget description should acknowledge any internal investments to support this work should the costs exceed the reimbursed amount.)

Description of the following, Optional (8 bonus points):

- ☐ Experience performing WGS of SARS-CoV-2 including duration and throughput or capacity. Describe the maximum cycle threshold (CT) of specimens successfully sequenced (5 bonus points).

- Experience and infrastructure to upload sequence data to NCBI and SRA (3 bonus points).

3. Statement of Need (25 points)

Description of the following:

- Infrastructure for obtaining SARS-CoV-2 specimens including who collects the specimens, quantity of specimens received by the laboratory per week, and percentage of positive specimens with a CT deemed appropriate by the laboratory for WGS (Total: 10 points).
  - Describe both the current infrastructure and, if necessary, any proposed modifications planned to meet the objectives of the RFP.
- The catchment area including a list of the counties and their population and number of current cases (8 points).
- How the specimens received or proposed for receipt represent the population in the respective catchment area and how this may be amended over time to ensure it remains representative of the general population (7 points).

4. Bidder Organization (5 points)

Description of the following:

- The institution's/laboratory's mission and services (2 points).
- How the proposal aligns with and supports the mission and services (3 points).

5. Program Activities (10 points)

Description of the following:

- The organizational structure of the proposed program, including essential staff and their qualifications (Licensure, Certification, Curricula Vitae) (3 points).
- The established relevant training and competency procedures for staff (5 points).
- The roles of the individuals that will complete the proposed plan (2 points).

Proposal Cover Page

RFP Title
RFP Number

Institution/laboratory Name
Mailing address
Telephone number

Lab Director, Technical Contact and Administrative Contacts:
Name(s)
Address(es)
Telephone number(s)
E-mail address(es)

Attachment 4

Status Updates

Biweekly Status Updates will include the following information:

(Note: NYS DOH will supply a template to the contract laboratories).

- Number of Specimens Received and Percentage with a sufficient CT to sequence
- Number of Specimens Sequenced
- Percentage of Specimens Sequenced in relation to Number of Positive Cases for each county in the catchment area
- Positivity rate for each county in the catchment area for the reporting period (County-level SARS-CoV-2 positive case data are available at https://forward.ny.gov/percentage-positive-results-county-dashboard and https://health.data.ny.gov)
- Number of Results uploaded to GISAID
    - If 10% or more results were not uploaded to GISAID, explain why
- Describe any Issues or Concerns (including challenges meeting objectives)

Attachment 5

Adverse Event Report

(Next page)

NYS SARS-CoV-2 WGS Partnership Adverse Event Report

Purpose:
The purpose of this document is to facilitate communication between the Wadsworth Center and contract laboratories in the NYS SARS-CoV-2 WGS consortium if an issue or error occurs with SARS-CoV-2 sequencing for this contract. The use of this form may be initiated by either the Wadsworth Center or a contract laboratory for transfer/exchange of information. When an issue is identified, please investigate the matter thoroughly, complete this form, when applicable, institute preventative measures, and submit a copy of the form to the Wadsworth Center.

PART I

Issue identified:
The person or laboratory that identifies the issue should complete Part I of this form. If Wadsworth identifies an issue, they will complete and send the form to the designated contract laboratory personnel. If a contract laboratory identifies an issue, they will complete this form and forward it to the Wadsworth Center at COVID19.Sequencing.Labs@health.ny.gov

Issue identified by: (name/laboratory) _____

Date: _____

Specimen ID number(s) affected:_____

Issue identified:

- ☐ Trouble obtaining samples
- ☐ Specimen contamination
- ☐ Incorrect lineage assignment
- ☐ Higher than expected QC failures
- ☐ Significant reagent failure
- ☐ Significant instrument failure
- ☐ Significant upload delay
- ☐ Other

Incident description:
Please provide additional details.

PART II

Review and follow up mitigation activities:
Please describe the outcome of the laboratory's internal review of the issue, and any findings that can be mitigated by preventative actions to prevent future occurrences. This can include activities already in place.

Form completed by: (Name/laboratory) _____

Date: _____

Please submit completed form and documentation to COVID19.Sequencing.Labs@health.ny.gov