Heluna Health
EMPOWERING POPULATION HEALTH INITIATIVES SINCE 1969

13300 Crossroads Parkway North, Suite 450 | City of Industry, CA | 91746
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WORK ORDER AGREEMENT

This Work Order Agreement (this "Agreement") is hereby made by and between Public Health Foundation Enterprises, Inc. DBA Heluna Health, a 501(c)(3) California nonprofit corporation (hereafter "HELUNA HEALTH", or "Client"), and the Local Health Department identified below (hereafter "Local Health Department") and sets forth the terms and conditions between Client and Local Health Department, for agreed services, as required by the Client, and as stated in this Agreement. This Agreement does not designate Local Health Department as the agent or legal representative of HELUNA HEALTH for any purpose whatsoever. (HELUNA HEALTH and Local Health Department shall be referred to herein individually as a "party" and collectively as the "parties").

I. IDENTIFIED PARTIES

CLIENT
Heluna Health
13300 Crossroads Parkway North, Suite 450
City of Industry, CA 91746
www.helunahealth.org
ATTN: Rochelle McLaurin, Deputy Director
ELCCOVID19Invoices@helunahealth.org

LOCAL HEALTH DEPARTMENT
County of Humboldt
Department of Health and Human Services – Public Health
529 I Street
Eureka, CA 95501
ATTN: Michele Stephens, Director
MStephens@co.humboldt.ca.us
(707) 268-2120

Grant#: 6NU50CK000539-01-10 DHHS-CDC CFDA#: 93.323

Program#: 0187.0170

II. TERM. Unless otherwise terminated or extended by written notice, the term of this Agreement shall commence on **12/2/2020** and term on **7/31/2021**.

III. SERVICES AND COMPENSATION. Local Health Department shall perform the services (the "Services") described below and as described in Attachment A, Statement of Work ("SOW") attached hereto and incorporated herein by this reference. The Services will take place at the location as referenced in Section 1. Identified Parties for Local Health Department and at such other location as may be set forth in the SOW.

(a) Services. Local Health Department shall perform all services as stated in the SOW. Local Health Department shall perform the Services in accordance with generally accepted professional standards and in an expeditious and economical manner consistent with sound professional practices. Local Health Department maintains and shall maintain at all times during the term of this Agreement all applicable federal, state and local business and other licenses, including any professional licenses or certificates, industrial permits and/or licenses, industry specific licenses, licenses required by the state(s) and/or locality(s) in which it does business, fictitious business names, federal tax identification numbers, insurance, and anything else required of Local Health Department as a business operator or to perform the Services.

(b) Payment. HELUNA HEALTH agrees to compensate the Local Health Department on a **Cost-Reimbursable Contract. See Attachment A "Budget" for line item budget detail**. Local Health Department shall be compensated only for Services actually performed and required as set forth herein and any services in excess will not be compensated. The total compensation payable to the Local Health Department hereunder shall be as set forth below: A total to not exceed **$83,333.33**.

If for any reason Local Health Department receives an overpayment of amount described above, Local Health Department shall promptly notify HELUNA HEALTH or such and repay said amount to HELUNA HEALTH within 10 days of demand for such repayment.

(c) Invoice. Invoices shall be submitted: **Quarterly, No Later than 30 Days after quarter end. See Attachment C for "Required Invoice Template."**

Payment for all undisputed amounts of submitted invoices shall be paid no later than 30 days after HELUNA HEALTH's receipt of the invoice and required back up documentation. Local Health Department shall submit invoices to the attention of the contact person identified by HELUNA HEALTH. All final invoices must be received within 45 days of the expiration or termination of this Agreement or within such earlier time period as HELUNA HEALTH may require. If any invoices are not submitted within such time periods, Local Health Department waives all rights to payment under such invoices. Local Health Department shall be solely responsible for the payment of all federal, state and local income taxes, social security taxes, federal and state unemployment insurance and similar taxes and all other assessments, taxes, contributions or sums payable with respect to Local Health Department or its employees as a result of or in connection with the Services performed by Local Health Department hereunder.

(d) Budget Modifications.

The budget may be modified accordingly:

- Informal Budget Modification: Two (2) times throughout the term of this agreement. The informal budget modification must be a change of <10% of the total budget. The request must be in writing to ELCCOVID19Invoices@helunahealth.org. Any informal budget modification request must be submitted thirty (30) days before the end of the agreement term.
- Formal Budget Modification: Two (2) times throughout the term of this agreement. The formal budget modification must be a change of 10% or greater of the total budget. The request must be in writing on agency letterhead to ELCCOVID19Invoices@helunahealth.org. Any formal budget modification request must be submitted sixty (60) days before the end of the agreement term.

IV. INSURANCE. Local Health Department, at its sole cost and expense, shall at all times during the term of this Agreement maintain the insurance coverage set forth on Attachment B, attached hereto and incorporated herein by this reference, on the terms and conditions described therein. Evidence of such insurance coverage shall be provided to HELUNA HEALTH by Local Health Department prior to commencing performance of the Services under this Agreement in the form of a Certificate of Insurance or Certificate of Self-Insurance.

V. AUTHORIZED SIGNERS. The undersigned certify their acknowledgment of the nature and scope of this agreement and support it in its entirety.

Signature & Date **Heluna Health**	**Signature & Date** **County of Humboldt** **Department of Health and Human Services – Public Health**
	Name & Title

TERMS AND CONDITIONS

1. **INDEPENDENT LOCAL HEALTH DEPARTMENT RELATIONSHIP**. Nothing herein is intended to place the parties in the relationship of employer-employee, partners, joint venturers, or in anything other than an independent Local Health Department relationship. Local Health Department shall not be an employee of HELUNA HEALTH for any purposes, including, but not limited to, the application of the Federal Insurance Contribution Act, the Social Security Act, the Federal Unemployment Tax Act, the provisions of the Internal Revenue Code, the State Revenue and Taxation Code relating to income tax withholding at the source of income, the Workers' Compensation Insurance Code 401(k) and other benefit payments and third party liability claims.

   Local Health Department shall retain sole and absolute discretion and judgment in the manner and means of carrying out Local Health Department's Services hereunder. Local Health Department is in control of the means by which the Services are accomplished. Any advice given to Local Health Department regarding the Services shall be considered a suggestion only, not an instruction. HELUNA HEALTH retains the right, but does not have the obligation, to inspect, stop, or alter the work of Local Health Department to assure its conformity with this Agreement. Local Health Department shall be responsible for completing the Services in accordance with this Agreement and within the time period and schedule set forth in the SOW, but Local Health Department will not be required to follow or establish a regular or daily work schedule.

2. **FEDERAL, STATE, AND LOCAL PAYROLL TAXES.** Neither federal, nor state, nor local income tax nor payroll taxes of any kind shall be withheld or paid by HELUNA HEALTH on behalf of Local Health Department or the employees of Local Health Department. Local Health Department shall not be treated as an employee with respect to the services performed hereunder for federal or state tax purposes.

   Local Health Department understands that Local Health Department is responsible to pay, according to law, Local Health Department's income taxes. If Local Health Department is not a corporation or other legal entity, Local Health Department further understands that Local Health Department may be liable for self-employment (social security) tax, to be paid by Local Health Department according to law. Local Health Department agrees to defend, indemnify and hold HELUNA HEALTH harmless from any and all claims made by federal, state and local taxing authorities on account of Local Health Department's failure to pay any federal, state or local income and self- employment taxes or other assessments due as a result of Local Health Department's Services hereunder. Furthermore, to avoid conflict with federal or state regulations, Local Health Department will not be eligible for employment with HELUNA HEALTH within the same calendar year in which Local Health Department performed services for HELUNA HEALTH.

3. **FRINGE BENEFITS.** Because Local Health Department is an independent entity, Local Health Department is not eligible for, and shall not participate in, any HELUNA HEALTH pension, health, or other fringe or employee benefit plans. Only personnel hired as HELUNA HEALTH employees will receive fringe benefits.

4. **WORKERS' COMPENSATION.** No workers' compensation insurance shall be obtained by HELUNA HEALTH concerning Local Health Department or the employees of Local Health Department. All persons hired by Local Health Department to assist in performing the tasks and duties necessary to complete the Services shall be the employees of Local Health Department unless specifically indicated otherwise in an agreement signed by all parties. Local Health Department shall immediately provide proof of insurance, including Workers' Compensation insurance and General Liability insurance, covering said employees, upon request of HELUNA HEALTH.

5. **EQUIPMENT AND SUPPLIES.** Local Health Department or Jurisdiction shall provide all necessary equipment, materials and supplies required by Local Health Department to perform the Services.

6. **TERMINATION.** HELUNA HEALTH may terminate this Agreement without cause at any time by giving written notice to Local Health Department at least 15 days prior to the effective date of termination. Either party may terminate this Agreement with reasonable cause effective immediately by giving written notice of termination for reasonable cause to the other party. Reasonable cause shall mean: (A) material violation or breach of this Agreement; (B) any act of the other party that exposes the terminating party to liability to others for personal injury or property damage or any other harm, damage or injury; (C) cancellation or reduction of funding affecting the Program affecting the Services; or (D) improper use of funds. In the event this Agreement is terminated for reasonable cause by HELUNA HEALTH, Local Health Department shall not be relieved of any liability to HELUNA HEALTH for damages and HELUNA HEALTH may withhold any payments to Local Health Department for the purpose of setoff until such time as the actual amount of damages due to HELUNA HEALTH from Local Health Department is determined.

   Upon the expiration or termination of this Agreement, Local Health Department shall immediately return to HELUNA HEALTH all computers, cell phones, smart phones, computer programs, files, documentation, user data, media, related material, finished or unfinished documents, studies, reports and any and all Confidential Information (as defined below) and Work Product (as defined below). HELUNA HEALTH shall have the right to withhold final payment to Local Health Department until all such items are returned to HELUNA HEALTH.

   These Terms and Conditions and any other provisions of this Agreement that by their nature should or are intended to survive the expiration or termination of this Agreement shall survive and the parties shall continue to comply with the provisions of this Agreement that survive. Notwithstanding any termination that may occur, each party shall continue to be responsible for carrying out all the terms and conditions required by law to ensure an orderly and proper conclusion.

7. **COMPLIANCE WITH LAWS.** Local Health Department shall comply with all state and federal statutes and regulations applicable to Local Health Department, the Services and the Program in performing Local Health Department's obligations under this Agreement. Local Health Department represents and warrants that neither Local Health Department nor its principals or personnel are presently, nor will any of them be during the term of this Agreement, debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any federal department or funding agency.

8. **HIPAA (if applicable).** In the event that Local Health Department's performance under this Agreement may expose Local Health Department to individually identifiable health information or other medical information governed by the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as amended, and any regulations promulgated in connection thereto, then Local Health Department agrees to execute and deliver a copy of HELUNA HEALTH's standard Business Associate Agreement or Business Associate sub Local Health Department Agreement, as applicable, as required by HIPAA.

9. **CONFIDENTIALITY AND NON-DISCLOSURE.** HELUNA HEALTH and Local Health Department agree that during the course of this Agreement, Local Health Department may be exposed to and become aware of certain unique and confidential information and special knowledge (hereinafter "Confidential Information") provided to or developed by HELUNA HEALTH and/or Local Health Department. Said Confidential Information includes, but is not limited to, the identity of actual and potential clients of HELUNA HEALTH, client lists, particular needs of each client, the manner in which business is conducted with each client, addresses, telephone numbers, and specific characteristics of clients; financial information about HELUNA HEALTH and/or its clients; client information reports; mailing labels; various sales and marketing information; sales report forms; pricing information (such as price lists, quotation guides, previous or outstanding quotations, or billing information); pending projects or proposals; business plans and projections, including new product, facility or expansion plans; employee salaries; contracts and wage information; mailing plans and programs; technical know-how; designs; products ordered; business methods; processes; records; specifications; computer programs; accounting; and information disclosed to

HELUNA HEALTH by any third party which HELUNA HEALTH is obligated to treat as confidential and/or proprietary.

Local Health Department expressly acknowledges that the Confidential Information constitutes confidential, valuable, special and unique assets of HELUNA HEALTH or, if applicable, any third-parties who may have disclosed Confidential Information to HELUNA HEALTH and that the Confidential Information belongs to and shall remain the property of HELUNA HEALTH and such third-parties. Local Health Department further expressly acknowledges that the Confidential Information derives independent actual or potential economic value from not being generally known to the public or to other persons and Local Health Department agrees to afford HELUNA HEALTH protection against any unauthorized use of the Confidential Information or any use of the Confidential Information in any manner that may be detrimental to HELUNA HEALTH.

Therefore, Local Health Department agrees to hold any and all Confidential Information in the strictest of confidence, whether or not particular portions or aspects thereof may also be available from other sources. Local Health Department shall not disclose Confidential Information in any manner whatsoever, directly or indirectly, or use it in any way whatsoever, either during the term of this Agreement or at any time thereafter, except solely for the purpose of performance under this Agreement. Further, Local Health Department shall develop and maintain procedures and take other reasonable steps in furtherance of HELUNA HEALTH's desire to maintain the confidentiality of the Confidential Information.

All documents and other items which might be deemed the subject of or related to Confidential Information of HELUNA HEALTH's business, whether prepared, conceived, originated, discovered, or developed by Local Health Department, in whole or in part, or otherwise coming into Local Health Department's possession, shall remain the exclusive property of HELUNA HEALTH and shall not be copied or removed from the premises of HELUNA HEALTH without the express written consent of HELUNA HEALTH. All such items, and any copies thereof, shall be immediately returned to HELUNA HEALTH by Local Health Department upon request at any time and upon termination of this Agreement. This section shall survive expiration or termination of this Agreement.

10. **NON-SOLICITATION OF EMPLOYEES.** During the term of this Agreement and for two years following its termination, Local Health Department shall not induce, encourage, or advise any person who is employed by or is engaged as an agent or independent Local Health Department by HELUNA HEALTH to leave the employment of HELUNA HEALTH or otherwise raid the employees of HELUNA HEALTH, without the express written consent of HELUNA HEALTH. Nothing contained in this paragraph shall constitute a waiver by HELUNA HEALTH of any rights it may have if Local Health Department engages in actionable conduct after the two-year period referred to above.

11. **WORKS FOR HIRE.** Local Health Department agrees that all inventions, original works of authorship, developments, concepts, know-how, discoveries, ideas, logos, improvements, trade secrets, secret processes, patents, patent applications, software, platforms, service marks, trademarks, trademark applications, copyright and copyright registrations, whether or not patentable or registerable under copyright, trademark or other similar laws, made, conceived or developed by Local Health Department, in whole or in part, either alone or in connection with others, that relate to the Services under this Agreement or the operations, activities, research, investigation, business or obligations of HELUNA HEALTH (collectively, the "Work Product") are the sole property of the HELUNA HEALTH and all right, title, interest and ownership in all such Work Product, including but not limited to copyrights, trademarks, patents, trade secret rights, trade names, and know-how and the rights to secure any renewals, reissues, and extensions thereof, will vest in the HELUNA HEALTH. The Work Product will be deemed to be "works made for hire" under United States copyright law (17 U.S.C. Section 101 et seq.) and made in the course of this Agreement, and Local Health Department expressly disclaims any interest in the Work Product.

To the extent that the Work Product may not, by operation of law, vest in the HELUNA HEALTH or may not be considered to be works made for hire, all right, title and interest therein are hereby irrevocably assigned to the HELUNA HEALTH. Local Health Department understands that HELUNA HEALTH may register the copyright, trademark, patent and other rights in the Work Product in HELUNA HEALTH's name and Local Health Department grants HELUNA HEALTH the exclusive right, and appoints HELUNA HEALTH as attorney-in-fact, to execute and prosecute in Local Health Department's name as author or inventor or in HELUNA HEALTH's name as assignee, any application for registration or recordation of any copyright, trademark, patent or other right or interest in or to the Work Product, and to undertake any enforcement action with respect to any Work Product. Local Health Department hereby agrees to sign such applications, documents, assignment forms and other papers as the HELUNA HEALTH requests from time to time to further confirm this assignment and Local Health Department agrees to give the HELUNA HEALTH and any person designated by the HELUNA HEALTH any reasonable assistance required to perfect and enforce the rights defined in this section. Local Health Department further understands that the HELUNA HEALTH has full, complete and exclusive ownership of the Work Product. In the event the aforementioned assignment is invalid, Local Health Department grants HELUNA HEALTH a non-exclusive, worldwide, perpetual, fully paid-up, irrevocable, right and license to use, reproduce, make, sell, perform and display (publicly or otherwise), and distribute, and modify and otherwise make derivative works of the Work Product and to authorize third parties to perform any or all of the foregoing on its behalf, including through multiple tiers of sublicenses. Local Health Department agrees not to use the Work Product Property for the benefit of anyone other than HELUNA HEALTH without HELUNA HEALTH's prior written permission.

All rights, interest and ownership to the Work Product granted or assigned to HELUNA HEALTH hereunder shall be subject to any rights of the Program under HELUNA HEALTH's agreement with the Program and any rights of the United States Federal Government under applicable laws and regulations.

12. **INDEMNITY.** Local Health Department hereby agrees to indemnify, hold harmless and defend HELUNA HEALTH, its board of trustees, officers, directors, agents, Local Health Departments, subcontractors, employees, affiliated companies, representatives, and agents (collectively, the "Local Health Department Indemnified Parties") from and against any and all claims, causes of action, costs, demands, lawsuits, expenses (including, without limitation, attorney's fees and costs), interest, penalties, losses, damages, settlements, liabilities, and any and all amounts paid in investigation or defense incurred by any of the Local Health Department Indemnified Parties arising out of or resulting from: (i) Local Health Department's (or its agents', subcontractors' or employees') performance of the Services; (ii) Local Health Department's (or its agents', subcontractors' or employees') default, non-performance or breach of this Agreement, including any representations, warranties, or certifications; (iii) any alleged or actual acts or omissions of Local Health Department (or its agents, subcontractors or employees) relating to services provided outside the scope of this Agreement; (iv) Local Health Department's (or its agents', subcontractors' or employees') violation of any federal, state or local law or regulation; or (v) any claims or actions that the Work Product, or any element thereof, infringes the intellectual, privacy or other rights of any party.

If any lawsuit, enforcement or other action is filed against any of the Local Health Department Indemnified Parties Local Health Department for which the Local Health Department Indemnified Parties are entitled to indemnification pursuant to this Agreement, Local Health Department and such other Local Health Department Indemnified Parties may elect to have Local Health Department, Local Health Department's sole expense, take control of the defense and investigation of such lawsuit or action using attorneys, investigators and others reasonably satisfactory to Local Health Department. The parties shall cooperate in all reasonable respects with the investigation, trial, and defense of any such lawsuit or action and any appeal arising from it. The terms of this section shall survive the termination of this Agreement.

13. **RECORD RETENTION AND ACCESS TO RECORDS.** Local Health Department agrees to retain all books, documents, papers, files, accounts, fiscal data, records, and reports relating to this Agreement or the Services, including, but not limited to, evidence pertaining costs and expenses, payment information, accounts of services provided and any other information or documentation related to Local Health Department's performance under this Agreement. Local Health Department shall retain all such records for a period of not less than seven (7) years after final payment is made under this Agreement and all pending matters are closed or longer if required by (i) HELUNA HEALTH's record retention policy, (ii) the Program, or (iii) any other applicable laws or regulations, including under the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards issued by the federal Office of Management Budget codified at 2 CFR Part 200 ("Uniform Guidance") and Federal Acquisition Regulation (FAR) System regulations at 48 CFR 4.700 et seq. Notwithstanding the foregoing, in the event any litigation, claim, negotiation, audit or other action is commenced prior to the expiration of the aforementioned retention period, all records related to such litigation, claim, negotiation, audit or other action shall be retained until full completion and resolution of the litigation, claim, negotiation, audit or other action.

Local Health Department agrees that HELUNA HEALTH, the Program, the U.S. Comptroller General and their respective authorized representatives or designees shall have the right, upon demand, to access, examine, copy, audit or inspect any and all of the records described in this section, including on-site audits, reviews and copying of records. The terms of this section shall survive expiration or termination of the Agreement.

14. **AMENDMENTS.** Amendments to this Agreement shall be in writing, signed by the party to be obligated by such amendment and attached to this Agreement.

15. **GOVERNING LAW; VENUE.** This Agreement shall be interpreted, construed and governed by, in accordance with and consistent with the laws of the State of California without giving effect to its conflicts of laws principals. The sole, exclusive and proper venue for any proceedings brought to interpret or enforce this Agreement or to obtain a declaration of the rights of the parties hereunder shall be Los Angeles County, California. Each of the parties hereto submits to the exclusive personal jurisdiction of the courts located in Los Angeles County, California and waives any defense of forum non conveniens.

16. **EQUITABLE RELIEF.** In light of the irreparable harm to HELUNA HEALTH that a breach by Local Health Department of Sections 9, 10 and 11 of these Terms and Conditions would cause, in addition to other remedies set forth in this Agreement

and other relief for violations of this Agreement, HELUNA HEALTH shall be entitled to enjoin Local Health Department from any breach or threatened breach of such Sections, to the extent permitted by law and without bond.

17. **FAIR INTERPRETATION.** The language appearing in all parts of this Agreement shall be construed, in all cases, according to its fair meaning in the English language, and not strictly construed for or against any party hereto. This Agreement has been prepared jointly by the parties hereto after arm's length negotiations and any uncertainty or ambiguity contained in this Agreement, if any, shall not be interpreted or construed against any party, but according to its fair meaning applying the applicable rules of interpretation and construction of contracts.

18. **NO WAIVER.** No failure or delay by any party in exercising a right, power or remedy under the Agreement shall operate as a waiver of any such right or other right, power or remedy. No waiver of, or acquiescence in, any breach or default of any one or more of the terms, provisions or conditions contained in this Agreement shall be deemed to imply or constitute a waiver of any other or succeeding or repeated breach or default hereunder. The consent or approval by any party hereto to or of any act of the other party hereto requiring further consent or approval shall not be deemed to waive or render unnecessary any consent or approval to or of any subsequent similar acts.

19. **NOTICES.** Any notice given in connection with this agreement shall be in writing and shall be delivered either by hand to the party or by certified mail, return receipt requested, to the party at the party's address stated in Section 1: Identified Parties. Any party may change its address stated herein by giving notice of the change in accordance with this paragraph.

20. **REMEDIES NON-EXCLUSIVE.** Except where otherwise expressly set forth herein, all remedies provided by this Agreement shall be deemed to be cumulative and additional and not in lieu of or exclusive of each other or of any other remedy available to the respective parties at law or in equity.

21. **SEVERABILITY**. If any term, provision, condition or other portion of this Agreement is determined to be invalid, void or unenforceable by a forum of competent jurisdiction, the same shall not affect any other term, provision, condition or other portion hereof, and the remainder of this Agreement shall remain in full force and effect, as if such invalid, void or unenforceable term, provision, condition or other portion of this Agreement did not appear herein.

22. **NON-ASSIGNABILITY.** This agreement shall not be assigned, in whole or in part, by Local Health Department without the prior written approval and consent of HELUNA HEALTH.

23. **COUNTERPARTS**. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original and all of which together shall constitute one instrument. Any signed counterpart delivered by electronic mail or facsimile shall be deemed for all purposes to constitute such party's good and valid execution and delivery of this Agreement.

24. **FEDERAL TERMS AND CONDITIONS**.

    A. Equal Employment Opportunity. Except as otherwise provided under 41 CFR Part 60, to the extent this Agreement meets the definition of a "federally assisted construction contract" as set forth in 41 CFR Part 60-1.3, Local Health Department agrees at all times during the term of this Agreement to comply with and abide by the following: (i) the equal opportunity clause ("Equal Opportunity Clause") in 41 CFR 60-1.4(b) in accordance with Executive Order 11246, as amended by Executive Order 11375 and that the Equal Opportunity Clause is a part of this Agreement and incorporated herein by this reference; and (ii) the regulations implementing the Equal Opportunity Clause at 41 CFR Part 60 and that such implementing regulations are a part of this Agreement and incorporated herein by this reference.

    B. Davis-Bacon Act and Copeland "Anti-Kickback" Act. To the extent this Agreement is for construction services (new construction or repair), Local Health Department agrees at all times during the term of this Agreement to comply with and abide by: (i) the terms of the Davis-Bacon Act, codified at 40 U.S.C. 3141 et seq., as supplemented by regulations at 29 CFR Part 5, and that such terms and regulations are a part of this Agreement and incorporated herein by this reference; and (ii) the terms of the Copeland "Anti-Kick Back" Act, codified at 40 U.S.C. § 3145 et seq., as supplemented by 29 CFR 3, and that such terms and regulations are a part of this Agreement and incorporated herein by this reference

    C. Contract Work Hours and Safety Standards Act. To the extent this Agreement is in excess of $100,000 and involves the employment of mechanics or laborers, Local Health Department agrees at all times during the term of this Agreement to comply with and abide by the terms of the Contract Work Hours and Safety Standards Act, codified at 40 U.S.C. 3701 et seq., as supplemented by regulations at 29 CFR Part 5, and that such terms and regulations are a part of this Agreement and incorporated herein by this reference.

    D. Clean Air Act and Federal Water Pollution Control Act. To the extent this Agreement is in excess of $150,000, Local Health Department agrees at all times during the term of this Agreement to comply with and abide by the standards, orders or regulations issued pursuant to the Clean Air Act, codified at 42 U.S.C. 7401 et seq. and the Federal Water Pollution Control Act codified at 33 U.S.C. 1251 et seq. Local Health Department further agrees to report any violations of the foregoing to HELUNA HEALTH and the Regional Office of the Environmental Protection Agency.

    E. Debarment and Suspension Certification. Local Health Department certifies that neither Local Health Department nor any of Local Health Department's agents, sub Local Health Departments or employees who may perform services under this Agreement are debarred, suspended or excluded from participation in any federal assistance programs in accordance with Executive Orders 12549 and 12689 and its implementing guidelines. Local Health Department agrees to immediately notify HELUNA HEALTH if Local Health Department or any of Local Health Department's agents, sub Local Health Departments or employees who may perform services under this Agreement become debarred, suspended or excluded from participation in federal assistance programs or federal contract transactions.

    F. Byrd Anti-Lobbying Amendment Certification. To the extent this Agreement is in excess of $100,000, Local Health Department certifies that neither Local Health Department nor any of Local Health Department's agents, sub Local Health Departments or employees who may perform services under this Agreement have not used and will not use any Federally 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. Local Health Department agrees to immediately notify HELUNA HEALTH if Local Health Department or any of Local Health Department's agents, sub Local Health Departments or employees who may perform services under this Agreement influence or attempt to influence any 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.

ATTACHMENT A

Statement of Work (SOW), Protocol, and Budget

Statement of Work

Local health departments (LHDs) participating in the CDPH Community Sentinel COVID-19 Surveillance, also known as CalSRVSS, agree to the following:

PARTICIPANT ENROLLMENT AND DATA COLLECTION

- ❑ Enroll individuals who meet the following eligibility criteria:

- Visit one of the selected testing sites, and
- Present with mild or asymptomatic illness. Asymptomatic individuals should not make up more than 20% of participants enrolled per week. Mildly ill individuals that meet clinical criteria below should be prioritized. Listed symptoms should be new or worsening (i.e., exclude those reporting chronic symptoms due to long-term comorbid conditions):

  - At least two of the following symptoms (if individual is non-verbal [e.g. infant] at least one of the following is sufficient):
    - Fever (measured or subjective)
    - Cough
    - Shortness of breath or difficulty breathing
    - Chills or rigors
    - Myalgia
    - Headache
    - Sore throat
    - New olfactory or taste disorder(s)
    - Congestion or runny nose
    - Nausea or vomiting
    - Diarrhea
    - Fatigue

- Have been notified about SARS-CoV-2 testing either verbally or in writing

- ❑ Collect a respiratory specimen from enrolled individuals for SARS-CoV-2 and respiratory viral panel test per current CDC guidance for SARS-CoV-2[1]
- ❑ Collect required data elements (and preferred data elements, if possible) on enrolled individuals per protocol (attached).

LABORATORY TESTING

- ❑ All sites agree that:
  - A maximum of 50 specimens per week will be shipped to the VRDL.
  - Specimens submitted to the VRDL for SARS-CoV-2 or respiratory viral panel (RVP) testing will be submitted with either:
    - A test requisition to be completed electronically using a computer: https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/VRDL_General_Purpose_Specimen_Submittal_Form.pdf. Once the form is completed on the

computer, sites agree to print it out and include ONE completed form for EACH specimen submitted.
OR

- A group file accessioning form (contact the VRDL at 510-307-8585 if interested in batch submittal of specimens)

- Sites will abide by the following storage and shipping requirements:
  - Specimens should be kept refrigerated at 4°C and shipped on cold packs if they can be received by the lab in less than 3 days (72 hours) of collection date.
  - If samples cannot be received by the laboratory in less than 3 days of the collection date, they should be frozen at -70°C or below and shipped on dry ice.
- Prior to shipping to the VRDL, sites will notify the VRDL of their shipment by secure email at VRDL.Mail@cdph.ca.gov
- Sites will ship a maximum of 50 specimens, at least weekly, to:

  CDPH VRDL
  Attn: Specimen Receiving
  850 Marina Bay Parkway
  Richmond, CA 94804

- ❑ Sites acknowledge and agree to provide the VRDL with both 1mL of original specimen and any remaining extract for each specimen submitted
- ❑ Sites acknowledge that they were informed that:
  - SARS-CoV-2 testing performed at the VRDL is diagnostic and turnaround time is approximately 3 business days (thus not including weekends and holidays) from receipt of the specimens at the VRDL
  - The primary purpose of RVP testing is for surveillance purposes
    - Negative RVP results cannot be reported as diagnostic
    - Positive RVP results can be reported as diagnostic
    - Turnaround time for RVP testing is 2 to 3 weeks
- ❑ If the VRDL will perform both SARS-CoV-2 testing and a full RVP, the local Public Health Laboratory agrees to send the original specimen to the VRDL. Please complete a submittal form or group file accessioning form as described above.
- ❑ If the local Public Health Laboratory will perform SARS-CoV-2 testing but will not perform a full RVP (e.g. no testing for other respiratory viruses, only influenza testing, etc.), the local Public Health Laboratory agrees to send a split of the original specimen (at least 1mL) to the VRDL for all or some RVP testing AND any remaining extract from the local Public Health Laboratory SARS-CoV-2 testing. Please complete a submittal form or group file accessioning form as described above and include the result of the SARS-CoV-2 testing as well as other respiratory testing, if any, conducted by the Public Health Laboratory.
  - If 1mL aliquots of original specimens will not be received by the VRDL in less than 3 days of the collection date, they should be frozen at -70°C or below and shipped on dry ice.
  - Please store remaining extracts at -70°C or below and ship on dry ice.
  - Please keep the 1mL of original specimen paired with its corresponding extract when shipped to the VRDL (on dry ice).

- ❑ If possible, the LHJ and local Public Health Laboratory agree to share SARS-CoV-2 extract CT or RLU values with VRDL to facilitate selection of specimens for whole genome sequencing (WGS). Values are to be included on the electronic laboratory submittal form or by including on the patient data linelist sent to the CalSRVSS epidemiology team. For sites performing their own WGS on SARS-CoV-2 extracts (internally or at another facility), sites agree to share results or WGS-related identifiers with the CalSRVSS epidemiology team, if possible.

WEEKLY DATA TRANSMISSION TO CDPH

- ❑ As soon as possible each week, transmit complete data on all enrolled the week prior
    - If sites will use CalREDIE for data management, sites agree to:
        - Enter data into CalREDIE per the attached protocol**AND**
        - Email a line list of enrolled individual CalREDIE incident IDs (or name and date of birth) to CDPH (COVCommunitySurveillance@cdph.ca.gov) via secure email
    - If sites will not use CalREDIE for data management, sites agree to:
        - Email a linelist of complete data for all enrolled individuals to CDPH (COVCommunitySurveillance@cdph.ca.gov) via secure email
        - Note: It is preferred that sites do not use CalREDIE for data management and transmission
    - If laboratory results are pending for a participant, those results can be submitted the following week
- ❑ If possible, transmit weekly healthcare facility data from the week prior to CDPH via email (COVCommunitySurveillance@cdph.ca.gov) using Appendix E
- ❑ If possible, transmit weekly CT/RLU values or WGS results/identifiers from the week prior to CDPH on the laboratory submittal form or via email (COVCommunitySurveillance@cdph.ca.gov) as part of the patient linelist.

[1] Centers for Disease Control and Prevention. Coronavirus Disease 2019 (COVID-19) Guidelines for Clinical Specimens. https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html

REPORTING

- ❑ The LHDs will provide quarterly progress reports to CDPH in a format that CDPH will provide.
- ❑ **Required Disclosures for Federal Awardee Performance and Integrity Information System (FAPIIS):** Consistent with 45 CFR 75.113, applicants and recipients must disclose in a timely manner, in writing to the CDC, with a copy to the HHS Office of Inspector General (OIG), all information related to violations of federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the federal award. Subrecipients must disclose, in a timely manner in writing to the prime recipient (pass through entity) and the HHS OIG, all information related to violations of federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the federal award. Disclosures must be sent in writing to the CDC and to the HHS OIG at the following addresses:

    CDC, Office of Grants Services
    Karen Zion, Grants Management Specialist
    Centers for Disease Control and Prevention
    Infectious Disease Services Branch
    2939 Flowers Road, MS-TV-2
    Atlanta, GA 30341

Telephone: 770-488-2729
Email: wvf8@cdc.gov (Include “Mandatory Grant Disclosures” in subject line)

AND

U.S. Department of Health and Human Services
Office of the Inspector General
ATTN: Mandatory Grant Disclosures, Intake Coordinator
330 Independence Avenue, SW
Cohen Building, Room 5527
Washington, DC 20201

Fax: (202)-205-0604 (Include “Mandatory Grant Disclosures” in subject line) or
Email: MandatoryGranteeDisclosures@oig.hhs.gov

Recipients must include this mandatory disclosure requirement in all subawards and contracts under this award.

Failure to make required disclosures can result in any of the remedies described in 45 CFR 75.371. Remedies for noncompliance, including suspension or debarment (See 2 CFR parts 180 and 376, and 31 U.S.C. 3321).

CDC is required to report any termination of a federal award prior to the end of the period of performance due to material failure to comply with the terms and conditions of this award in the OMB-designated integrity and performance system accessible through SAM (currently FAPIIS). (45 CFR 75.372(b)) CDC must also notify the recipient if the federal award is terminated for failure to comply with the federal statutes, regulations, or terms and conditions of the federal award. (45 CFR 75.373(b))

PERSONNEL MANAGEMENT

At your agency’s discretion, budgeted staff can be hired within your agency or with the assistance of Heluna Health. If your agency prefers Heluna Health to hire staff on its behalf, please notify Cheryl Starling. Please note, if Heluna Health hires any staff, your agency must provide a duty statement in the Heluna Health format. Additionally, Heluna Health may have duty statements for comparable positions that can be reviewed and edited.

Protocol

Background

Since the emergence of coronavirus disease 2019 (COVID-19) in California in January 2020, the California Department of Public Health (CDPH) and local public health partners have been tracking and monitoring COVID-19 cases in California and have implemented containment and mitigation efforts. Due to limitations on supplies for specimen collection (e.g., swabs, media), laboratory testing (e.g., test kits and reagents), and personal protective equipment [PPE], the diagnosis of COVID-19, as of April 2020, has focused primarily on people who have traveled to countries first impacted by the disease (e.g., China), have been a close contact of a confirmed case, or have had severe disease requiring hospitalization. These limitations have inhibited the ability of public health to estimate background disease prevalence, particularly among people with mild disease who may add to identified cases to represent how much COVID-19 is within the community and are an important group to help estimate true burden of disease. Estimates of disease prevalence among people who are mildly ill requiring outpatient care (i.e., urgent care, ER, drive-through testing) and with likely community transmission help public health make informed decisions about prevention and control of COVID-19, including measures such as social distancing.

In our first phase of community surveillance which was unfunded, two counties in California were able to implement surveillance, Santa Clara and Los Angeles. During March 5-14, 2020, Santa Clara County public health worked with local clinicians to conduct SARS-CoV-2 PCR testing on specimens from 79 patients who presented to urgent care with respiratory symptoms and who tested negative for influenza.[1] Of the 79 patients, 9 (11%) tested positive for SARS-CoV-2, helping to confirm community transmission in the county. Results of this analysis influenced in-county community mitigation strategies including canceling of mass gatherings and shelter-in-place orders. Independent from the CDC and CDPH-led community surveillance efforts, the Los Angeles County + University of Southern California Medical Center and the Los Angeles County Department of Public Health conducted sentinel community surveillance between March 12-13 and 15-16 and found that 7/131 (5.3%) specimens tested positive for SARS-CoV-2.[2] Of note, the Santa Clara surveillance project only tested influenza negative specimens for SARS-CoV-2, whereas the Los Angeles surveillance tested specimens for SARS-CoV-2 regardless of influenza results.

As community transmission of COVID-19 increases in California, sentinel community surveillance is essential to estimate disease prevalence over time, throughout the state, and among key groups (e.g., demographic groups at high risk for infection) in order to inform containment, mitigation and prevention measures, which may vary depending on regional COVID-19 epidemiology. Therefore, **CDPH and several California local health jurisdictions (LHJs) are working with the U.S. Centers for Disease Control and Prevention (CDC) to initiate sentinel community surveillance for COVID-19.** Los Angeles County will be independently implementing their own sentinel community surveillance for COVID-19, and their methods will be coordinated with CDPH.

Detecting community transmission by testing individuals with mild outpatient illness and understanding who those people are (e.g., by age groups, demographics, etc.) is critical for shaping response activities including testing criteria, quarantine guidance, investigation protocols, and additional public health preparedness measures. Most critically, data from this surveillance will guide decisions based on the effectiveness of implemented mitigation strategies (e.g., shelter-in-place orders) and how public health can most effectively utilize mitigation and containment strategies moving forward.

Objective

To conduct SARS-CoV-2 PCR and respiratory viral panel (RVP) testing of respiratory specimens from a convenience sample of patients who (a) visit select outpatient healthcare facilities or non-clinician based testing sites located in one of the community sentinel surveillance local health jurisdictions (b) present with mild or asymptomatic illness, and define who these people are in terms of age, demographics and occupation. Unlike typical surveillance activities, individual patients who test positive or inconclusive for COVID-19 will be notified of their test result and followed up with accordingly. In addition, it is important to gather denominator information, including estimates of population served, number of weekly visits to the testing site, number of patients who met clinical criteria, and the number with specimens collected and tested, overall and by age group.

Methods

Identifying Sentinel Outpatient Facility Sites

Participating LHJs should select one or more outpatient healthcare facility or mobile non-clinician directed testing sites (e.g., urgent care, emergency room, drive-through testing, pop-up clinic) located within their LHJ from which a total of 10-50 specimens per week can be submitted for SARS-CoV-2 PCR and RVP testing. Ideally, LHJs will collect patient data and specimens from a total of 30-50 patients per week across all enrolled facilities in their LHJ. LHJs can enroll >50 patients per week; however, if RVP testing will be done at the CDPH Viral and Rickettsial Disease Laboratory (VRDL) and not the local public laboratory, then the VRDL can only receive a maximum of 50 specimens per week per LHJ due to resource constraints.

Both adult and pediatric patients should be represented in weekly LHJ data, but individual healthcare sites do not need to see both adult and pediatric patients (i.e., LHJs could choose one adult and one pediatric site). LHJs can weigh more towards adult patients if a denominator is available among all people tested.

Other factors to consider when selecting a site include:

- Meet minimum weekly volume of patients for testing (30/week)
- Established ongoing relationship between LHJ and the testing site or previous experience with the site as a reliable study or surveillance partner
- If possible, LHJs may choose to select a testing site where the LHJ has easy access to the site medical records
- Sites physically near LHJ may help for specimen pick up or drop off each week, eliminating shipping costs
- Sites that represent the diversity and breadth of the LHJ population (e.g., demographics, socioeconomic factors, vulnerable populations)
- Sites that serve sub-populations that may be at higher risk for contracting and transmitting COVID-19 or developing severe disease such as populations who:
    - *Live in congregate settings*: Workers and residents of correctional facilities, long-term care or skilled nursing facilities, and on-campus university housing
    - *Do not or cannot routinely and easily access the healthcare system*: Persons experiencing homelessness, persons living in highly rural, isolated areas, certain immigrant populations, or people who might not otherwise get tested (i.e., testing deserts)
    - *Cannot abide by shelter-in-place or other mitigation orders*: Essential workers (e.g., healthcare workers [inpatient, ambulatory care, dentistry, etc.], delivery or grocery store workers), workers unable to telework, populations with high proportions of persons of lower socioeconomic status who may be financially unable to forgo work
    - *Are at higher risk of severe disease*: Elderly populations, populations at medical risk (e.g., chronic lung disease, severe asthma, heart conditions, immunocompromised, severe obesity, diabetes, chronic kidney disease undergoing dialysis, or liver disease)

Eligibility Criteria

Patient eligibility includes:

- Visit one of the selected testing sites, and
- Present with mild or asymptomatic illness. Asymptomatic patients should not make up >20% of county patient sample. Mildly ill patients should preferably meet the clinical criteria below. Listed symptoms should be <u>new or worsening</u> (i.e., exclude patients who chronically have these symptoms due to long-term comorbid conditions):

    - <u>At least two</u> of the following symptoms (if patient is non-verbal [e.g. infant] <u>at least one</u> of the following is sufficient):
        - Fever (measured or subjective)
        - Cough
        - Shortness of breath or difficulty breathing
        - Chills or rigors
        - Myalgia
        - Headache
        - Sore throat
        - New olfactory or taste disorder(s)
        - Congestion or runny nose
        - Nausea or vomiting
        - Diarrhea
        - Fatigue

- Have been notified about SARS-CoV-2 testing either verbally or in writing

Collection, Shipping, and Testing of Specimens

Participating testing sites will prospectively obtain respiratory specimens collected from patients who meet the above eligibility criteria using specimen collection and handling protocols recommended by current CDC guidance for SARS-CoV-2.[3] If more than one specimen type is collected, the specimens should be combined to maximize the number of patients that can be tested. For example, combine nasopharyngeal (NP) swab with oropharyngeal (OP) swab into one tube of viral transport medium if both specimen types are collected.

It is recommended that each testing site identify 1-2 healthcare providers who are willing to collect respiratory specimens, have knowledge of epidemiologic studies, and are available during the 3-6-month or longer surveillance period. Each testing site and provider can determine the dates and times of data collection each week. Participating healthcare providers will need to collect specimens while wearing all recommended PPE.

Clinical specimens from patients should have RVP and FDA-authorized SARS-CoV-2 molecular assay testing performed, ideally by a state or local public health laboratory. Respiratory specimens should be transported in accordance with CDC guidance.[3]

If the local public health laboratory (PHL) sends specimens to the CDPH VRDL for SARS-CoV-2 and/or RVP testing, the CalSRVSS program can support a maximum of 50 specimens per week per jurisdiction. Additionally specimens should be submitted using the appropriate test requisition form to be completed electronically (using a computer): https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/VRDL_General_Purpose_Specimen_Submittal_Form.pdf

Once the form is completed on the computer, please print it out and include ONE completed form for EACH specimen submitted. If you have several specimens to submit to the VRDL, please contact the VRDL at 510-307-8585 and request a group file accessioning form.

If the local PHL will perform SARS-CoV-2 testing but will not perform a full RVP (e.g. no testing for other respiratory viruses, only influenza testing, etc.), the local PHL can send a split of the original specimen (at least 1mL) to the VRDL for all or some RVP testing. Please complete a submittal form or group file accessioning form as described above.

Any questions about submitting specimens to the VRDL can be sent to VRDL.Mail@cdph.ca.gov or phoned to 510-307-8585.

The VRDL RVP includes the following respiratory viral pathogens through a single-plex wet assay:

	VRDL Resp PCR panel
1	Flu A
2	Flu A H1
3	Flu A H3
4	Flu B
5	Flu B Yamagata
6	Flu B Victoria
7	RSV
8	Adenovirus
9	Human Metapneumovirus
10	Parainfluenza Type 1
11	Parainfluenza Type 2
12	Parainfluenza Type 3
13	Parainfluenza Type 4

14 Human Coronavirus NL63
15 Human Coronavirus 229E
16 Human Coronavirus OC43
17 Human Coronavirus HKU1
18 Enterovirus
19 Rhinovirus
20 Mycoplasma (bacterium)

Patient-level Data Collection and Transmission

For each patient, collected data should include demographics, contact information, address, occupation, exposure and travel history, symptoms, onset date, specimen collection details, and results, as listed in Table 1. The provided data collection tool template (Appendix A) and participant intake form (Appendix B) can be customized and used by the testing site or LHJ, if helpful. Sites are not required to use these forms; however, data elements should be collected in the formats shown in these forms (e.g. response options to each question).

Per established electronic laboratory reporting (ELR) protocols for COVID-19, positive and negative SARS-CoV-2 results will come into the CalREDIE Disease Incident Staging Area (DISA) for either "Novel Coronavirus 2019 (nCov-2019)" or "Coronavirus disease 2019 – non-positive ELR" depending on whether results are positive or negative, respectively. These results can be imported into disease incidents in CalREDIE by LHJ staff, but this is not required. The required or preferred data elements below can either be entered into CalREDIE for data management or entered into the data collection tool in Appendix C.

TABLE 1. COVID-19 COMMUNITY & SENTINEL SURVEILLANCE DATA ELEMENTS

	DATA ELEMENT	REQUIRED	PREFERRED	IF APPLICABLE
JURISDICTION ID	Reporting jurisdiction	X		
	CalREDIE incident ID			X
	Local ID			X
	MRN			X
TESTING SITE	Testing facility/site name	X		
	Testing facility/site address	X		
	Testing facility/site type	X		
PATIENT	First name	X		
	Last name	X		
	Date of birth (mm/dd/yyyy)	X		
	Age		X	
	Gender	X		
	Race	X		
	Ethnicity	X		
	Address (Street, city, zip, county)	X		
	Phone number (xxx - xxx - xxxx)	X		
	Work (month prior)		X (highly)	
	Occupation (month prior)		X (highly)	
	Occupation Setting/Industry (month prior)		X (highly)	
	Work outside home (month prior)		X (highly)	
	Employer name		X	
	Homelessness (month prior)		X (highly)	
	Congregate living setting (month prior)		X (highly)	
	Comorbid conditions		X (highly)	
	Pregnant			X
	Travel history (month prior)		X	
	Sexual orientation		X	

TABLE 1. COVID-19 COMMUNITY & SENTINEL SURVEILLANCE DATA ELEMENTS

	DATA ELEMENT	REQUIRED	PREFERRED	IF APPLICABLE
CLINICAL	Symptoms	X		
	Onset date (mm/dd/yyyy)	X		
	Contact to case	X		
SPECIMEN	Ordering physician			X
	Specimen collection setting (e.g., in-office, drive-through)	X		
	Accession number		X	
	Collection date (mm/dd/yyyy)	X		
	Specimen type	X		
SARS-COV-2 RESULTS	Report date (mm/dd/yyyy)	X		
	Results	X		
RVP RESULTS	Report date (mm/dd/yyyy)	X		
	Results	X		
VACCINE DATA (NEW)	Why getting tested		X	
	Received COVID-19 vaccine	X		
	Plan to get vaccine		X	
	Dose/dates		X	

Complete data should be transmitted to CDPH weekly.

- LHJs who are collecting and managing data in CalREDIE, can enter all data into the CalREDIE incident, however, LHJs will also need to email CDPH a linelist of patient incident IDs (or patient name and date of birth) each week in order to identify patients who are part of this project. A guide for entering data into CalREDIE can be found in Appendix D.
- LHJs who are collecting and managing data independent of CalREDIE, can securely email CDPH each week with the completed data collection tool provided in Appendix C. Please note that it is preferred that sites do not use CalREDIE for data management and transfer.

VRDL RVP results will be transmitted directly from VRDL to the CDPH epidemiology team for this project.

CDPH will transmit weekly de-identified data to the CDC. Data will be presented in aggregate.

Facility-level Data Collection and Transmission

CDC is also requesting weekly facility-level data from participating healthcare facility sites to be used in COVID-19 modeling efforts. The objective of this data request is to gather the minimum data needed to provide a crude estimate of underlying burden of COVID-19 cases in each participating jurisdiction. **Please note that if collection, reporting, and transmission of these data are challenging, this piece of the project can wait until specimen and other data collection procedures have been established and refined.** CDPH will host a training call with CDC partners, likely in early July, on this piece to answer questions about data collection and transmission.

If possible, please provide values across all ages, and stratified by the following age groups: 0-4 years, 5-17 years, 18-49 years, 50-64 years, and ≥65 years. If it is not possible to provide values by facility, please provide value totals for all participating facilities in your jurisdiction, an estimate of the proportion each facility contributes, and the type of patient population served by the facility (e.g. pediatric).

Table 2 describes the data request from each participating site each week per CDC guidance. Please note that items A, B, and E from Table 2 have been deleted from the original protocol and now only items C and D are being requested. Data can be transmitted weekly to CDPH using the facility data collection tool in Appendix E.

TABLE 2. FACILITY-LEVEL DATA

	Value
C	Number of ILI visits or unique ILI patients seen at facility, per week
D	Number of total visits or unique patients seen at facility, per week

This data will be transmitted to CDC each week by CDPH.

Considerations for Individuals Tested

The activities under this surveillance are not considered research by CDC or CDPH. The specimens obtained will be collected as part of routine clinical care when investigating the cause of a respiratory illness or as a result of participation in another surveillance effort. However, specimens will be identifiable to LHJ and hospital/facility staff since finding a positive COVID-19 result does have implications for clinical management of the patient and disease control. As some COVID-19 patients initially present with mild illness only to return with more severe disease, identifying COVID-19 cases through this surveillance may benefit some patients as they would get more timely appropriate care if their illness worsens. In addition, the LHJs can then follow-up with the patient for appropriate investigation (e.g. contact tracing) and quarantine recommendations. Therefore, prior to specimen collection, each participating site must notify the patient of SARS-CoV-2 testing either verbally or in writing. Examples of notification options can be found in Appendix B.

Onboarding of Participating Testing Site(s)

Onboarding of participating testing sites is likely to require training of healthcare testing site administration, healthcare providers, and laboratory staff. Templates for such materials are provided in Appendix F.

Obtaining Supplies for this Surveillance Project

If an LHJ or testing site needs supplies for this project (e.g. PPE, swabs, media, test kits, reagents), the LHD should put in a formal request through their Medical Health Operational Area Coordination (MHOAC) for assistance and specify that supplies are being requested in support of CDPH COVID-1 Community & Sentinel Surveillance. If an LHD is still unable to obtain the necessary supplies through this mechanism, please contact CDPH for assistance.

Follow-up on Confirmed Cases of COVID-19

Upon identification of a confirmed case of COVID-19 through sentinel community surveillance, LHDs should follow-up with the patient and their healthcare providers per routine local COVID-19 protocols for management, containment, and infection control.

Considerations for when Current Containment Strategies May Change Based on Results of Testing

Data on community transmission collected through this will help inform local, statewide, and, potentially, national decisions on measures to limit spread of the virus, including the implementation, continuation, or termination of mitigation or containment efforts, such as shelter-in-place order.

Contact Information

CDPH contacts

- General CDPH Community & Sentinel Surveillance email address: covCommunitySurveillance@cdph.ca.gov
- Seema Jain, MD, Chief of the Disease Investigations Section (DIS), Infectious Diseases Branch, seema.jain@cdph.ca.gov, Cell: 415-699-1366, Work: 510-620-3444

- Debra Wadford, PhD, Chief of the Viral and Rickettsial Disease Laboratory
  debra.wadford@cdph.ca.gov, Cell: 510-685-2965, Work: 510-307-8624

- Gail Sondermeyer Cooksey, MPH, DIS Senior Epidemiologist
  gail.cooksey@cdph.ca.gov, Cell: 267-566-5197, Work: 510-620-3631

- Jake Pry, PhD, Senior Epidemiologist
  jake.pry@cdph.ca.gov

- Lauren Linde, MPH, Surveillance Epidemiologist
  lauren.linde@cdph.ca.gov

- Sam Schildhauer, MPH, Surveillance Epidemiologist
  samuel.schildhauer@cdph.ca.gov

Appendices

Appendix A. Data Abstraction Form	Appendix A. Data Abstraction Form_V
Appendix B. Participant Intake Form	Appendix B. Participant Intake Fc
Appendix C. Participant-level Data Collection Tool	Copy of Appendix C. Participant-level D
Appendix D. CalREDIE data entry	Appendix D. CalREDIE Data Entry
Appendix E. Modeling Activity Variables	Appendix E. Modeling Activity Va
Appendix F. Testing Site Onboarding	Appendix F. Onboarding Testing

References

1. Zwald ML, Lin W, Sondermeyer Cooksey GL, et al. Rapid Sentinel Surveillance for COVID-19 — Santa Clara County, California, March 2020. MMWR Morb Mortal Wkly Rep. ePub: 3 April 2020. DOI: http://dx.doi.org/10.15585/mmwr.mm6914e3
2. Spellberg B, Haddix M, Lee R, et al. Community prevalence of SARS-CoV-2 among patients with influenzalike illnesses presenting to a Los Angeles medical center in March 2020. JAMA 2020
3. Centers for Disease Control and Prevention. Coronavirus Disease 2019 (COVID-19) Guidelines for Clinical Specimens. https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html.

Budget

Expenditure Type	Expenditure Name	Max # of Hours (if hourly employee)	Monthly Salary/Hourly Range (per budget)	Salary/Hourly Rate	Total % Budgeted	Months Position Budgeted	Original Budget
Personnel							
Position 1							
Lead Communicable Disease Investigator I - Extra Help		100		$ 22.19		4	**$ 2,219.00**
Position 2							
Communicable Disease Investigator I - Extra Help		225		$ 21.11		4	**$ 4,749.75**
Position 3							
Community Health Outreach Worker I/II - Courier (3 hrs/week) & Specimen Receiving and Data Entry		360		$ 17.12		4	**$ 6,163.20**
Position 4							
Lab Assistant II - Specimen Processing Packaging and Shipping Extra Help		432		$ 21.04		4	**$ 9,089.28**
Position 5							
Microbiologist II - COVID-19 Testing		360		$ 28.84		4	**$ 10,382.40**
Position 6							
Lab Assistant II - Specimen Processing Packaging and Shipping		126		$ 21.00		4	**$ 2,646.00**
Total Salaries and Wages							**$ 32,603.63**
Total Fringe Benefits					**38.86%**		**$ 12,669.64**
Total Personnel							**$ 45,273.27**
Total Direct Cost							**$ 83,333.33**
Total Budget							**$ 83,333.33**

Total budget not to exceed $83,333.33.

ATTACHMENT B

Insurance Coverage Requirements

Local Health Department (and any sub Local Health Department may use if permitted under the Agreement) shall, at its own expense, obtain and maintain the following self-insurance coverage during all periods while providing services under the Agreement:

General Liability Insurance

(a) Coverage on an occurrence basis of all operations and premises, independent Local Health Departments, products, completed operations, explosion, collapse and underground hazards, broad form contractual liability, personal injury (including bodily injury and death), broad form property damage (including completed operations and loss of use) and additional insured endorsement.

(b) The minimum limits of liability under this insurance requirement shall be not less than the following:

(i)	General Aggregate Limit	$2,000,000
(ii)	Each Occurrence	$1,000,000

Workers Compensation & Employer's Liability Insurance

Coverage in accordance with all applicable state laws reflecting the following limits of liability

(b) Workers' Compensation:

(i) California Statutory Benefits

(b) Employer's Liability:

(i)	$1,000,000	Bodily Injury each Accident
(ii)	$1,000,000	Bodily Injury by Disease – Policy Limit
(iii)	$1,000,000	Bodily Injury by Disease – Each Employee

Comprehensive Automobile Liability Insurance

Coverage for all owned, hired and non-owned vehicles with limits not less than $1,000,000 combined single limit, bodily injury and property damage liability per occurrence with no annual aggregate limits.

Professional Liability Insurance

Coverage with minimum limits of liability not less than $1,000,000 each occurrence and $2,000,000 annual aggregate. To the extent coverage is afforded on a claims made basis, tail coverage for a minimum of three (3) years shall be required.

All insurance policies shall: (i) name HELUNA HEALTH and any related entities identified by HELUNA HEALTH as Additional Insureds on a primary basis; (ii) stipulate that the insurance is primary and that any insurance carried by any of said Additional Insureds shall be excess and non-contributory insurance; (iii) be provided by carriers rated by A.M. Best Company as "A- VII" or better and be admitted to conduct insurance business in California; (iv) not contain a deductible greater than $1,000; (v) provide that thirty (30) days written notification is to be given to HELUNA HEALTH prior to the non-renewal, cancellation or material alteration of any policy; and (vi) be acceptable to HELUNA HEALTH.

CERTIFICATE NO. ISSUE DATE

GL1-7476 AI	**CERTIFICATE OF COVERAGE**	08/10/2020

Public Risk Innovation, Solutions and Management
C/O ALLIANT INSURANCE SERVICES, INC.
PO BOX 6450
NEWPORT BEACH, CA 92658-6450

PHONE (949) 756-0271 / FAX (619) 699-0901
LICENSE #0C36861

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BELOW. THIS CERTIFICATE OF COVERAGE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED and/or requesting a WAIVER OF SUBROGATION, the Memorandums of Coverage must be endorsed. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

COVERAGE AFFORDED	**A- Public Risk Innovation, Solutions and Management**
COVERAGE AFFORDED	**B**
COVERAGE AFFORDED	**C**
COVERAGE AFFORDED	**D**

Member:
HUMBOLDT COUNTY
ATTN: RISK MANAGEMENT DIVISION
825 FIFTH STREET
EUREKA, CA 95501-1172

Coverages

THIS IS TO CERTIFY THAT THE MEMORANDUMS OF COVERAGE LISTED BELOW HAVE BEEN ISSUED TO THE MEMBER NAMED ABOVE FOR THE PERIOD INDICATED, NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN. THE COVERAGE AFFORDED BY THE MEMORANDUMS DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS, AND CONDITIONS OF SUCH MEMORANDUMS. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

CO LTR	TYPE OF COVERAGE	MEMORANDUM NUMBER	COVERAGE EFFECTIVE DATE	COVERAGE EXPIRATION DATE	LIABILITY LIMITS
A	[X] Excess General Liability [X] General Liability Aggregate [X] Auto Liability	PRISM 20 EL-04	07/01/2020	07/01/2021	$1,000,000 $2,000,000 $1,000,000 Limits inclusive of the Member's Self-Insured Retention of $100,000

Description of Operations/Locations/Vehicles/Special Items:

AS RESPECTS AGREEMENT BETWEEN HUMBOLDT COUNTY AND HELUNA HEALTH FOR FUNDING TO ENHANCE CAPACITY TO CONDUCT TESTING AND CONTRACT TRACING FOR COVID-19.

HELUNA HEALTH IS INCLUDED AS AN ADDITIONAL COVERED PARTY, BUT ONLY INSOFAR AS THE OPERATIONS UNDER THIS CONTRACT ARE CONCERNED.

THIS INSURANCE SHALL BE PRIMARY AND NO OTHER INSURANCE SHALL CONTRIBUTE PURSUANT TO ENDORSEMENT NUMBER U-9.

Certificate Holder

HELUNA HEALTH
13300 CROSSROADS PARKWAY NORTH, SUITE 450
CITY OF INDUSTRY, CA 91746

Cancellation

SHOULD ANY OF THE ABOVE DESCRIBED MEMORANDUMS OF COVERAGES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WIL BE DELIVERED IN ACCORDANCE WITH THE MEMORANDUMS OF COVERAGE PROVISIONS.

AUTHORIZED REPRESENTATIVE

Gina Dean

Public Risk Innovation, Solutions and Management

CERTIFICATE NO. ISSUE DATE

GL1-7477 CO

CERTIFICATE OF COVERAGE

08/10/2020

Public Risk Innovation, Solutions and Management

C/O ALLIANT INSURANCE SERVICES, INC.
PO BOX 6450
NEWPORT BEACH, CA 92658-6450

PHONE (949) 756-0271 / FAX (619) 699-0901
LICENSE #0C36861

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BELOW. THIS CERTIFICATE OF COVERAGE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED and/or requesting a WAIVER OF SUBROGATION, the Memorandums of Coverage must be endorsed. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

COVERAGE AFFORDED	**A- Public Risk Innovation, Solutions and Management**
COVERAGE AFFORDED	**B**
COVERAGE AFFORDED	**C**
COVERAGE AFFORDED	**D**

Member:
HUMBOLDT COUNTY
ATTN: RISK MANAGEMENT DIVISION
825 FIFTH STREET
EUREKA, CA 95501-1172

Coverages

THIS IS TO CERTIFY THAT THE MEMORANDUMS OF COVERAGE LISTED BELOW HAVE BEEN ISSUED TO THE MEMBER NAMED ABOVE FOR THE PERIOD INDICATED, NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN. THE COVERAGE AFFORDED BY THE MEMORANDUMS DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS, AND CONDITIONS OF SUCH MEMORANDUMS. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

CO LTR	TYPE OF COVERAGE	MEMORANDUM NUMBER	COVERAGE EFFECTIVE DATE	COVERAGE EXPIRATION DATE	LIABILITY LIMITS
A	[X] Excess General Liability [X] General Liability Aggregate	PRISM 20 EL-04	07/01/2020	07/01/2021	$1,000,000 $2,000,000 Limits inclusive of the Member's Self-Insured Retention of $100,000

Description of Operations/Locations/Vehicles/Special Items:

AS RESPECTS EVIDENCE OF COVERAGE AGREEMENT BETWEEN HUMBOLDT COUNTY AND HELUNA HEALTH FOR FUNDING TO ENHANCE CAPACITY TO CONDUCT TESTING AND CONTRACT TRACING FOR COVID-19.

COVERAGE INCLUDES ERRORS AND OMISSIONS.

Certificate Holder

HELUNA HEALTH
13300 CROSSROADS PARKWAY NORTH, SUITE 450
CITY OF INDUSTRY, CA 91746

Cancellation

SHOULD ANY OF THE ABOVE DESCRIBED MEMORANDUMS OF COVERAGES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WIL BE DELIVERED IN ACCORDANCE WITH THE MEMORANDUMS OF COVERAGE PROVISIONS.

AUTHORIZED REPRESENTATIVE

Gina Dean

Public Risk Innovation, Solutions and Management

CERTIFICATE NO. ISSUE DATE

WC-3075	**CERTIFICATE OF COVERAGE**	08/10/2020

PUBLIC RISK INNOVATION, SOLUTIONS AND MANAGEMENT

C/O ALLIANT INSURANCE SERVICES, INC.
PO BOX 6450
NEWPORT BEACH, CA 92658-6450

PHONE (949) 756-0271 / FAX (619) 699-0901
LICENSE #0C36861

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BELOW. THIS CERTIFICATE OF COVERAGE DOES NOT CONSTITITUE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER

IMPORTANT: If the certificate holder is requesting a WAIVER OF SUBROGATION, the Memorandums of Coverage must be endorsed. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

COVERAGE AFFORDED BY: **A - See attached schedule of insurers**

Member:
HUMBOLDT COUNTY
ATTN: RISK MANAGEMENT DIVISION
825 FIFTH STREET
EUREKA, CA 95501-1172

COVERAGE AFFORDED BY: **B**

COVERAGE AFFORDED BY: **C**

COVERAGE AFFORDED BY: **D**

Coverages

THIS IS TO CERTIFY THAT THE MEMORANDUMS OF COVERAGE AND POLICIES LISTED BELOW HAVE BEEN ISSUED TO THE MEMBER NAMED ABOVE FOR THE PERIOD INDICATED, NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN. THE COVERAGE AFFORDED BY THE MEMORANDUMS AND POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS, AND CONDITIONS OF SUCH MEMORANDUMS AND POLICIES.

CO LTR	TYPE OF COVERAGE	MEMORANDUM/ POLICY NUMBER	COVERAGE EFFECTIVE DATE	COVERAGE EXPIRATION DATE	LIABILITY LIMITS
A	WORKERS' COMPENSATION & EMPLOYERS' LIABILITY	See attached Schedule of Insurers for policy numbers	07/01/2020	07/01/2021	WORKERS' COMPENSATION: Statutory EMPLOYERS' LIABILITY: $5,000,000

LIMITS APPLY PER OCCURRENCE FOR ALL PROGRAM MEMBERS COMBINED.

Description of Operations/Locations/Vehicles/Special Items:

AS RESPECTS EVIDENCE OF COVERAGE AGREEMENT BETWEEN HUMBOLDT COUNTY AND HELUNA HEALTH FOR FUNDING TO ENHANCE CAPACITY TO CONDUCT TESTING AND CONTRACT TRACING FOR COVID-19.

Certificate Holder

HELUNA HEALTH
13300 CROSSROADS PARKWAY NORTH, SUITE 450
CITY OF INDUSTRY, CA 91746

Cancellation

SHOULD ANY OF THE ABOVE DESCRIBED MEMORANDUMS OF COVERAGE/POLICIES BE CANCELLED BEFORE THE EXPIRATION THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE MEMORANDUMS OF COVERAGE/POLICIES PROVISIONS.

AUTHORIZED REPRESENTATIVE

Gina Dean

Public Risk Innovation, Solutions and Management

ATTACHMENT C

Required Invoice Template
Draft

An example of the required invoice template is attached. The invoice template specific to your agency will be provided after the agreement is fully executed.

Invoice Instructions

The invoice template will be updated quarterly and provided the third week of month for the previous quarter.

Quarterly invoice template and supporting documentation are due within 30 days of quarter end via email to ELCCOVID19Invoices@helunahealth.org.

- Supporting documentation required: Invoice, proof of payment, receipts, and packing slips for any operating cost purchases (i.e. equipment, supplies, etc.).
- For personnel supporting documentation, please provide payroll register or general ledger detail for employees and timesheets.

INVOICE

Heluna Health
13300 Crossroads Parkway North, Suite 450
City of Industry, CA 91746
(800) 201-7320
ELCCOVID19Invoices@helunahealth.org

Name of Local Health Department _____
Local Health Department Address _____
Contact _____
Telephone # _____
Email _____

Program Number: _____ Invoice No: _____
Period Covered: _____ Date of Invoice: _____
Final: Yes_____ No_____

ITEM	Prior Month Expended	CURRENT EXPENSES	CUMULATIVE EXPENSES	APPROVED BUDGET	UNEXPENDED BALANCE
Non-Heluna Health Personnel Costs					
Position Title	$0.00	$0.00	$0.00	$0.00	$0.00
Total Salaries	$0.00	$0.00	$0.00	$0.00	$0.00
Total Benefits	$0.00	$0.00	$0.00	$0.00	$0.00
TOTAL NON-HELUNA HEALTH PERSONNEL COSTS	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**
Operating Costs					
Line 1	$0.00	$0.00	$0.00	$0.00	$0.00
Line 2	$0.00	$0.00	$0.00	$0.00	$0.00
Line 3	$0.00	$0.00	$0.00	$0.00	$0.00
Line 4	$0.00	$0.00	$0.00	$0.00	$0.00
TOTAL OPERATING COSTS	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**
TOTAL DIRECT COSTS	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**
Indirect Costs	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**
TOTAL INVOICE	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**

Please submit only one (1) invoice per month.
Due Date: Invoice and supporting documentation are due within 30 days of month end via email to ELCCOVID19Invoices@helunahealth.org.
Supporting documentation required: Invoice, proof of payment, receipts, and packing slips for any operating cost purchases (i.e. equipment, supplies, etc.).
For personnel supporting documentation, please provide payroll register or general ledger detail for employees and timesheets.

I certify that all expenditures reported are for appropriate purposes and in accordance with the terms and conditions of the agreement.

_____ _____
Signature Date

_____
Printed Name and Title

**********************Heluna Health Use Only**********************

Received on: _____

First Review & Date: _____

Approver & Date: _____

Date Sent to Accounting: _____

COVID-19 Community Sentinel Surveillance
Patient Data Abstraction Form
Jurisdiction: _____

CalREDIE ID: _____
Local ID: _____
MRN: _____

APPENDIX A
DATA ABSTRACTION FORM

[LOCAL HEALTH DEPARTMENT NAME] & California Department of Public Health
COVID-19 Community Sentinel Surveillance

Patient Data Abstraction Form

Please note that questions marked with a red asterisks (*) are required fields.

Healthcare Facility Data		
Healthcare facility/site name*		
Healthcare facility/site address*		
Healthcare facility/site type*	☐ Emergency room ☐ Urgent care ☐ Other: _____	☐ Pediatric clinic ☐ Primary care

Clinical Criteria	
To meet clinical criteria for this surveillance project, the patient must present with mild or asymptomatic illness. Mildly ill patients should preferably have at least two of the following new or worsening symptoms (i.e. exclude patients who chronically have these symptoms due to long-term comorbid conditions). For non-verbal patients (e.g. infants), only one symptom is necessary to qualify. Please check all symptoms that the patient exhibits.	
☐ Fever ☐ Cough ☐ Shortness of breath/difficulty breathing ☐ Chills or rigors ☐ Muscle aches/myalgia ☐ Fatigue	☐ Headache ☐ Sore throat ☐ Loss of taste or smell ☐ Nausea or vomiting ☐ Diarrhea ☐ Congestion or runny nose

Other Clinical Data	
Other symptoms not included in the clinical criteria:*	
~~☐ Vomiting~~ ~~☐ Nausea~~ ☐ Abdominal pain	~~☐ Diarrhea~~ ~~☐ Runny nose~~ ☐ Other: _____
Onset date (mm/dd/yyyy)*	
In the 14 days before the patient got sick, did they have close contact with anyone who was sick with COVID-19?*	☐ Yes ☐ No ☐ Unknown

Commented [CG1]: This form is a template to be used if helpful.

Your LHD or healthcare facility is welcome to edit this form (add fields, make additional fields required, or delete non-required fields that you do no plan to collect). You are also welcome to use a different mechanism to collect and record data. However, we do ask that the general questions and the exact answer options are used.

Commented [CG2]: Please note this is no longer an exclusion criterion. It is simply a data element to be collection

COVID-19 Community Sentinel Surveillance
Patient Data Abstraction Form
Jurisdiction: _____

CalREDIE ID: _____
Local ID: _____
MRN: _____

Basic Patient Data	
First name*	
Last name*	
Date of birth (mm/dd/yyyy) *	
Age	
Gender (check one)*	☐ Female ☐ Female-to-Male Transgender ☐ Male ☐ Male-to-Female Transgender ☐ Unknown ☐ Other: _____
Ethnicity (check one)*	☐ Hispanic/Latino ☐ Non-Hispanic/Non-Latino ☐ Unknown
Race (check all that apply)*	☐ African-American/Black ☐ American Indian or Alaska Native ☐ Asian *(check all that apply)* ☐ Asian Indian ☐ Japanese ☐ Cambodian ☐ Korean ☐ Chinese ☐ Laotian ☐ Filipino ☐ Thai ☐ Hmong ☐ Vietnamese ☐ Other:_____ ☐ Pacific Islander *(check all that apply)* ☐ Native Hawaiian ☐ Samoan ☐ Guamanian ☐ Other:_____ ☐ White ☐ Other:_____ ☐ Unknown
Address - Street*	
Address - City*	
Address - State*	
Address – Zip code (xxxxx)*	
Address – County residence	
Phone number (xxx - xxx - xxxx)*	

Potential exposure data in the month prior to illness onset	
Did the patient work at all in the month prior to onset?	☐ Yes ☐ No ☐ Unknown
If no, check all that apply:	☐ Child ☐ Student ☐ Retired ☐ Unemployed

If yes, complete the work-related questions below:	
Occupation (in the month prior to onset)	
Occupation setting or industry (in the month prior to onset) (e.g. healthcare, childcare, construction site)	
Did the patient work outside the home in the month prior to onset?	☐ Yes ☐ No ☐ Unknown
Employer name:	
Was the patient experiencing homelessness in the month prior to onset?	☐ Yes ☐ No ☐ Unknown
Was the patient living in a congregate setting (e.g. skilled nursing facility, prison/jail, on-campus university housing) in the month prior to onset?	☐ Yes ☐ No ☐ Unknown *If yes, what type? :*_____ _____
Did the patient travel outside of the county, state, or country in the month prior to onset?	☐ Yes ☐ No ☐ Unknown *If yes*, please specify below: _____ _____ _____

Additional Patient Data	
If applicable, pregnant?	☐ Yes ☐ No ☐ Unknown
Did the patient have any of the following comorbid conditions?	☐ None ☐ Diabetes ☐ Cardiovascular disease ☐ Hypertension ☐ Asthma ☐ Chronic lung disease ☐ Chronic kidney disease ☐ Chronic liver disease ☐ Stroke ☐ Neurologic / neuro-developmental ☐ Cancer ☐ Immuno-compromised ☐ Obesity ☐ Unknown ☐ Other: _____
Has the patient ever smoked tobacco/cigarettes/vaped?	☐ Current smoker ☐ Former smoker ☐ Current e-cig/vape use

	☐ Former e-cig/vape use ☐ No
Sexual orientation	☐ Heterosexual / Straight ☐ Gay / Lesbian / Homosexual ☐ Bisexual ☐ Other: _____ ☐ Don't know ☐ Refuse to answer

Laboratory testing data	
Ordering physician	
Specimen collection setting*	☐ In-office ☐ Drive through ☐ Other: _____
Specimen accession number	
Collection date (mm/dd/yyyy) *	
Type of specimen*	☐ Nasopharyngeal (NP) ☐ Oropharyngeal (OP) ☐ Combined NP/OP ☐ Other: _____

Notes

COVID-19 Community Sentinel Surveillance
Participant Data Abstraction Form
Facility/Testing Site name: _____

CalREDIE ID: _____
Local ID: _____
MRN: _____

APPENDIX B
PARTICIPANT INTAKE FORM

[LOCAL HEALTH DEPARTMENT NAME] & California Department of Public Health
COVID-19 Community Sentinel Surveillance

The information collected in this form is vital to better understand how COVID-19 is impacting communities in California. If a parent or guardian is answering for a child or another person in their care, note that all questions are regarding the patient. Please note that you may refuse to answer any question that you do not feel comfortable answering.

Participant information

First Name: _____ Last Name: _____

Address: _____

City: _____ State: _____ Zip: _____

Phone: _____ Date of Birth (mm/dd/yyyy) : _____/_____/_____ Age: _____

What is your gender? (check one)
☐ Female ☐ Female-to-Male Transgender ☐ Other: _____
☐ Male ☐ Male-to-Female Transgender

Are you Hispanic, Latino/a, or Spanish origin? (check one) ☐ Yes ☐ No ☐ Don't know / Not sure

Which one or more of the following would you say is your race? (check all that apply)
☐ African American / Black ☐ American Indian / Alaska Native ☐ Asian
☐ Pacific Islander ☐ White ☐ Other:_____

If Asian, (check all that apply)
☐ Asian Indian ☐ Cambodian ☐ Chinese
☐ Filipino ☐ Hmong ☐ Japanese
☐ Korean ☐ Laotian ☐ Thai
☐ Vietnamese ☐ Other: _____

If Pacific Islander: (check all that apply)
☐ Native Hawaiian ☐ Guamanian ☐ Samoan
☐ Other: _____

Clinical information:

In the past 14 days, did you have close contact with anyone who was sick with COVID-19?
☐ Yes ☐ No ☐ Don't know / Not sure

Commented [CG1]: This form is a template to be used if helpful.

Your LHD or healthcare facility is welcome to edit this form (add fields, make additional fields required, or delete non-required fields that you do no plan to collect). You are also welcome to use a different mechanism to collect and record data. However, we do ask that the general questions and the exact answer options are used.

Commented [CG2]: We delete the introduction paragraph for this project but you may add it back in or add your own if you wish:

[Healthcare facility name] is partnering with the [Local Health Department] and the California Department of Public Health to conduct community and sentinel surveillance for COVID-19 and other respiratory pathogens. As part of this public health surveillance, patients are asked to complete the form below and to have a sample taken that will be tested for SARS-CoV-2, the virus that causes COVID-19, and for other respiratory viruses, such as influenza. If you are positive for SARS-CoV2, you will be notified within about a week. If you are positive for other respiratory viruses, you will be notified within 2-3 weeks. If you have any questions about this surveillance project, please contact [appropriate email address]. *If a parent or guardian is answering these questions for a child or another person in their care, note that all questions are regarding the patient.*

COVID-19 Community Sentinel Surveillance
Participant Data Abstraction Form
Facility/Testing Site name: _____

CalREDIE ID: _____
Local ID: _____
MRN: _____

Around when did you first start feeling sick? (mm/dd/yyyy) _____/_____/_____

Below is a list of symptoms, please check any symptom that you have had related to your current illness. If you regularly have any of these symptoms due to a chronic medical condition, only check the box if the symptom became worse during this illness.

☐ Fever
☐ Chills or rigors
☐ Muscle aches/myalgia
☐ Headache
☐ Vomiting
☐ Nausea
☐ Abdominal pain
☐ Fatigue
☐ Cough
☐ Shortness of breath/difficulty breathing
☐ Sore throat
☐ Loss of taste or smell
☐ Diarrhea
☐ Runny nose
☐ Other symptoms: _____
☐ No symptoms

Next we have some questions about <u>the month before you got sick</u>.

Did you work at all <u>in the month before you got sick</u>?

☐ Yes – If yes, please complete the questions in the box below
☐ No – If no, please check all that apply: ☐ Child ☐ Student ☐ Retired ☐ Unemployed

What kind of work did you do? For example, registered nurse, janitor, cashier, auto mechanic.

_____

What kind of business or industry did you work in? For example, hospital, elementary school, clothing manufacturing, restaurant. _____

<u>In the month before you got sick</u>, did you work outside the home? (check one)
☐ Yes ☐ No ☐ Don't know / Not applicable

Employer name: _____

<u>In the month before you got sick</u>, did you experience homelessness or were you unstably housed (e.g., couch surfing, sleeping in your car)? (check one)
☐ Yes ☐ No ☐ Don't know / Not sure

<u>In the month before you got sick</u>, did you live in a congregate setting? For example, a skilled nursing facility, prison / jail, on-campus university housing. (check one)
☐ Yes – If yes, what type: _____ ☐ No ☐ Don't know / Not sure

<u>In the month before you got sick</u>, did you travel outside of the county, state, or country? (check one) ☐ Yes ☐ No ☐ Don't know / Not sure

If yes, where did you travel to*?* _____

_____

Lastly, we have a few personal questions:

COVID-19 Community Sentinel Surveillance
Participant Data Abstraction Form
Facility/Testing Site name: _____

CalREDIE ID: _____
Local ID: _____
MRN: _____

To your knowledge, are you now pregnant? (check one) ☐ Yes ☐ No ☐ Don't know / Not sure

Have you been diagnosed with any of the following conditions?

☐ None
☐ Cancer
☐ Chronic lung disease
☐ Immunocompromising condition
☐ Stroke
☐ Asthma
☐ Chronic kidney disease
☐ Diabetes
☐ Neurologic or neuro-developmental condition
☐ Cardiovascular disease
☐ Chronic liver disease
☐ Hypertension
☐ Obesity

Have you ever smoked tobacco/cigarettes/vaped?

☐ Yes, current smoker
☐ Yes, current e-cig/vape use
☐ Yes, former smoker
☐ Yes, former e-cig/vape use
☐ No

The final question is about sexual orientation. Which of the following best represents how you think of yourself? (check one)

☐ Heterosexual / Straight
☐ Other: _____
☐ Gay / Lesbian / Homosexual
☐ Don't know / Not sure
☐ Bisexual
☐ Refuse to answer

Thank you for completing this survey.

FOR HEALTH DEPARTMENT OR HEALTHCARE FACILITY USE ONLY:
Facility address: _____ Ordering Physician: _____
Facility type: ☐ ER ☐ Urgent care ☐ Primary care ☐ Pediatric clinic ☐ Other_____
Specimen collection setting: ☐ In-office ☐ Drive through ☐ Other: _____
Specimen accession number: _____ Collection date (mm/dd/yyyy) : _____/_____/_____
Type of specimen: ☐ NP ☐ OP ☐ Combined NP/OP ☐ Other:_____

APPENDIX C
PARTICIPANT-LEVEL DATA COLLECTION TOOL

Data element	Required	Data type	Data options
ReportingJursidiction	X	Text - Categorical	Butte; Contra Costa; Humboldt; Imperial; Marin; San Diego; San Luis Obispo; Santa Clara; Tulare; Ventura; Yolo
CalREDIE_IncidentID		Text	
Local_ID		Text	
MRN		Text	
Healthcare_Facility_Name	X	Text	
Healthcare_Facility_Address			
Healthcare_Facility_City			
Healthcare_Facility_Zip			
Healthcare_Facility_Type	X	Text - Categorical	Emergency room; Urgent care; Pediatric clinic; Primary care; Other
Healthcare_Facility_Type_Other		Text	
Last_Name	X	Text	
First_Name	X	Text	
DOB	X	Date	
Age		Numeric	
Gender	X	Text - Categorical	Female; Male; Female-to-Male Transgender; Male-to-Female Transgender; Unknown; Other
Gender_Other		Text	
Race	X	Text	African American/Black; American Indian or Alaska Native; Asian; Pacific Islander; White; Other
Race_Other		Text	
Asian_Specify		Text'	Asian Indian; Cambodian; Chinese; Filipino; Hmong; Japanese; Korean; Laotian; Thai; Vietnamese; Other
Asian_Specify_Other		Text	
PacificIslander_Specify		Text	Native Hawaiian; Samoan; Guamanian; Other
PacificIslander_Other		Text	
Ethnicity	X	Text - Categorical	Hispanic/Latino; Non-Hispanic/Non-Latino; Unknown
Street_Address	X	Text	
City	X	Text	
State	X	Text	
Zip	X	Numeric	
County_Residence	X	Text	
Phone_Number	X	Numeric	###-###-####
Onset_date	X	Date	MM/DD/YYYY
Fever	X	YN	Yes; No; Unknown
Subjective_Fever	X	YN	Yes; No; Unknown
Chills	X	YN	Yes; No; Unknown
Muscle_Aches	X	YN	Yes; No; Unknown
Headache	X	YN	Yes; No; Unknown
Sore_Throat	X	YN	Yes; No; Unknown
Loss_TasteSmell	X	YN	Yes; No; Unknown
Cough	X	YN	Yes; No; Unknown
SOB	X	YN	Yes; No; Unknown
Vomitting_Nausea	X	YN	Yes; No; Unknown
Abdominal_Pain	X	YN	Yes; No; Unknown
Diarrhea	X	YN	Yes; No; Unknown
Runny_Nose	X	YN	Yes; No; Unknown
Other_Symptoms	X	YN	Yes; No; Unknown
Other_Symptoms_Specify	X	Text	
Contact_to_Case	X	YN	Yes; No; Unknown
Work		YN	Yes; No; Unknown
Work_No_Child		YN	Yes; No; Unknown
Work_No_Student		YN	Yes; No; Unknown
Work_No_Retired		YN	Yes; No; Unknown
Work_No_Unemployed		YN	Yes; No; Unknown
Occupation		Text	
Occupation_Setting		Text	
Work_Outside_Home		YN	Yes; No; Unknown
Employer_Name		Text	
Homelessness		YN	Yes; No; Unknown
Congregate_Living		YN	Yes; No; Unknown
Congregate_Living_Specify		Text	
Travel		YN	Yes; No; Unknown
Travel_Location1		Text	
Travel_Location2		Text	
Travel_Location3		Text	
Pregnant		YN	Yes; No; Unknown
Comorb_None		YN	Yes; No; Unknown
Comorb_Diabetes		YN	Yes; No; Unknown
Comorb_CVD		YN	Yes; No; Unknown
Comorb_HTN		YN	Yes; No; Unknown
Comorb_Asthma		YN	Yes; No; Unknown
Comorb_CLD		YN	Yes; No; Unknown
Comorb_CKD		YN	Yes; No; Unknown
Comorb_Liver		YN	Yes; No; Unknown
Comorb_Stroke		YN	Yes; No; Unknown
Cormorn_Neuro		YN	Yes; No; Unknown
Comorb_Cancer		YN	Yes; No; Unknown
Comorb_Immuno		YN	Yes; No; Unknown
Comorb_Obesity		YN	Yes; No; Unknown
Comorb_CurrSmoke		YN	Yes; No; Unknown
Comorb_FormSmoke		YN	Yes; No; Unknown
Comorb_ECigVape		YN	Yes; No; Unknown
Comorb_Unknown		YN	Yes; No; Unknown
Comorb_Other		YN	Yes; No; Unknown
Comorb_Other_Specify		Text	
SexualOrientation		Text - Categorical	Heterosexual/Straight; Gay/Lesbian/Homosexual; Bisexual; Other; Unknown; Decline to answer
SexualOrientation_Other			
OrderingPhysician		Text	
Specimen_Collection_Setting	X	Text - Categorical	In-office; Drive through; Other
Specimen_Collection_Setting_Other	X	Text	
Specimen_Accession_Number	X	Text	
Specimen_Collection_Date	X	Date	MM/DD/YYYY
Specimen_Type	X	Text - Categorical	Nasopharyngeal; Oropharyngeal; Nasopharyngeal/Oropharyngeal; Other
Specimen_Type_Other			
SARSCOV2_Result	X	Text - Categorical	Positive; Negative; Equivocal; Pending; Note done
Flu_A_Result		Text - Categorical	Positive; Negative; Equivocal; Pending; Note done
Flu_A_H1_Result		Text - Categorical	Positive; Negative; Equivocal; Pending; Note done
Flu_A_H3_Result		Text - Categorical	Positive; Negative; Equivocal; Pending; Note done
Flu_B_Result		Text - Categorical	Positive; Negative; Equivocal; Pending; Note done
Flu _B_Yamagata_Result		Text - Categorical	Positive; Negative; Equivocal; Pending; Note done
Flu_B_Victoria_Result		Text - Categorical	Positive; Negative; Equivocal; Pending; Note done
RSV_Result		Text - Categorical	Positive; Negative; Equivocal; Pending; Note done
Adenovirus_Result		Text - Categorical	Positive; Negative; Equivocal; Pending; Note done
Human_Metapneumovirus_Result		Text - Categorical	Positive; Negative; Equivocal; Pending; Note done
Parainfluenza_Type_1_Result		Text - Categorical	Positive; Negative; Equivocal; Pending; Note done
Parainfluenza_Type_2_Result		Text - Categorical	Positive; Negative; Equivocal; Pending; Note done
Parainfluenza_Type_3_Result		Text - Categorical	Positive; Negative; Equivocal; Pending; Note done
Parainfluenza_Type_4_Result		Text - Categorical	Positive; Negative; Equivocal; Pending; Note done
Human_Coronavirus_NL63_Result		Text - Categorical	Positive; Negative; Equivocal; Pending; Note done
Human_Coronavirus_229E_Result		Text - Categorical	Positive; Negative; Equivocal; Pending; Note done
Human_Coronavirus_OC43_Result		Text - Categorical	Positive; Negative; Equivocal; Pending; Note done
Human_Coronavirus_HKU1_Result		Text - Categorical	Positive; Negative; Equivocal; Pending; Note done
Enterovirus_Result		Text - Categorical	Positive; Negative; Equivocal; Pending; Note done
Rhinovirus_Result		Text - Categorical	Positive; Negative; Equivocal; Pending; Note done
Mycoplasma_Result		Text - Categorical	Positive; Negative; Equivocal; Pending; Note done
RVP_Results		Text - Categorical	Pending; All Negative, Positive, Not Tested

APPENDIX D
CALREDIE DATA ENTRY

Guidance for CalREDIE Data Entry
Patient Data Abstraction Form

Note: Negative SARS-CoV-2 results will come into the CalREDIE Disease Incident Staging Area (DISA) via electronic laboratory report (ELR) as a "Coronavirus Disease 2019 - Non-positive ELR" condition that does not include the PUI and Epi Form tab. In order to fill in all of the required information for patients with negative results, you will have to import the incident into the "Novel Coronavirus 2019 (nCoV-2019)" condition and then change the Resolution Status to "Not a Case".

IDs	CalREDIE tab	CalREDIE Field
CalREDIE ID	Will be assigned automatically	
Local ID	Case Investigation	Notes/Remarks
MRN	Case Investigation	Notes/Remarks

Healthcare facility data	CalREDIE tab	CalREDIE Field
Healthcare facility name*	Case Investigation	Reporting Source – Provider **OR** Notes/Remarks
Healthcare facility type*	Case Investigation	Notes/Remarks – *There is no other field for this question.*

Clinical Criteria:	CalREDIE tab	CalREDIE Field
Onset date (mm/dd/yyyy)*	PUI & Epi Form	Ever symptomatic? – *Response: Yes* **AND** If yes, date of first symptom onset
Symptoms*	PUI & Epi Form	Signs and symptoms (mark all that apply).
Contact to case*	PUI & Epi Form	Have close contact with a laboratory confirmed COVID-19 case?

Basic Patient Data	CalREDIE tab	CalREDIE Field
First name*	Patient	First Name
Last name*	Patient	Last Name
Date of birth (mm/dd/yyyy) *	Patient	DOB (MM/DD/YYYY)
Age	Patient	Age

Basic Patient Data	CalREDIE tab	CalREDIE Field
Gender (check one)*	Patient	Gender
Race (check all that apply)*	Patient	Race
Ethnicity (check one)*	Patient	Ethnicity
Address - Street*	Patient	Address Number & Street
Address - City*	Patient	City
Address - State*	Patient	State
Address – Zip code (xxxxx)*	Patient	Zip
Address – County residence	Patient	County of Residence
Phone number (xxx - xxx - xxxx)*	Patient	Home Telephone **OR** Cellular Phone **OR** Work/School Telephone

Potential exposure data in the month prior to illness onset	CalREDIE tab	CalREDIE Field
Did you work at all in the month before you got sick? If so, what kind of work did you do? For example, registered nurse, janitor, cashier, auto mechanic. If no, list all that apply: Child, Student, Retired, Unemployed	Patient	If yes: Occupation (note the occupation options in CalREDIE are limited so please use the Other category when needed to specify) OR If no: fill in other options that apply in the Occupation—Describe/Specify field
What kind of business or industry did you work in? For example, hospital, elementary school, clothing manufacturing, restaurant?	Patient	Occupation Setting (note the occupation setting options in CalREDIE are limited so please use the Other category when needed to specify)
In the month before you got sick, did you work outside the home?	Patient	Occupation location – Note “worked outside home”
Employer name	Patient	Occupation – Describe/Specify (note there is no field for this in CalREDIE)
Was the patient experiencing homelessness in the month prior to onset?*	PUI & Epi Form	Housing status – *Response: Unstably housed*
Was the patient living in a congregate setting (e.g. skilled nursing facility,	PUI & Epi Form	Staff or resident at a congregate setting? –

prison/jail, on-campus university housing) in the month prior to onset?		*Response: Yes, resident* **AND** Congregate setting
Did the patient travel outside of the county, state, or country in the month prior to onset?	PUI & Epi Form	TRAVEL HISTORY

Additional patient data	CalREDIE tab	CalREDIE Field
If applicable, pregnant?	Patient	Pregnant?
Did the patient have any of the following comorbid conditions in the month prior to onset?	PUI & Epi Form	Does the patient have any comorbid conditions? (mark all that apply)
Smoker	PUI & Epi Form	Does the patient have any comorbid conditions? (mark all that apply)
Sexual orientation (check one)	PUI & Epi Form	What is the patient's sexual orientation?

Laboratory testing data	CalREDIE tab	CalREDIE Field
Note: SARS-CoV-2 results that are reported via ELR will appear automatically in the Lab Tab under Laboratory Information w/Provider & Facility (system) section. PLEASE re-enter the data as specified below to make it easier to distinguish results from this surveillance project from other laboratory results that may be received for this patient.		
Specimen collection setting*	Laboratory Info (LABORATORY TESTING – Novel-CoV rRT-PCR)	Where was testing performed? – *Response: COMMUNITY SURVEILLANCE [enter setting type]*
Specimen accession number	Laboratory Info	*Will automate in ELR message*
Collection date (mm/dd/yyyy) *	Laboratory Info (LABORATORY TESTING – Novel-CoV rRT-PCR)	Collection date
Type of specimen*	Laboratory Info (LABORATORY TESTING – Novel-CoV rRT-PCR)	Specimen type
SARS-Cov-2 result	Laboratory Info (LABORATORY TESTING – Novel-CoV rRT-PCR)	Result
RVP result data	Laboratory Info (LABORATORY TESTING – GENERAL NON-	These data do not need to be entered in CalREDIE if RVP is being performed by VRDL. The CDPH

	Novel-COV PATHOGEN)	epidemiology team will get those results directly from VRDL.

Notes	CalREDIE tab	CalREDIE Field
	Case Investigation	Notes/Remarks

APPENDIX E
MODELING ACTIVITY VARIABLES

	Values	All ages	0-4 years	5-17 years	18-49 years	50-64 years	65+ years
C	Number of ILI visits or unique ILI patients seen at facility, per week						
D	Number of total visits or unique patients seen at facility, per week						

[OPTIONAL: ADD LETTERHEAD]

APPENDIX F
TESTING SITE ONBOARDING

[LOCAL HEALTH DEPARTMENT]
[LHD CONTACT]
[LOCAL COVID-19 WEBPAGE]

California Department of Public Health
https://www.covid19.ca.gov/

Commented [CG1]: Please note, LHD and healthcare facilities do not need to use this letter or guidance document. It is simply here as a template that can be edited and used, if helpful.

[DATE]

To [HEALTHCARE FACILITY NAME] staff,

Since the emergence of coronavirus disease 2019 (COVID-19) in California in January 2020, [LOCAL HEALTH DEPARTMENT] in collaboration with the California Department of Public Health (CDPH) have been tracking and monitoring COVID-19 cases in [COUNTY] and implemented containment and mitigation efforts. Due to supply limitations and other barriers, diagnosis of COVID-19, as of May 2020, has focused primarily on people who had traveled to countries first impacted by the disease (e.g., China), had been a close contact of a confirmed case or with severe disease requiring hospitalization. These limitations have inhibited the ability of public health to estimate background disease prevalence, particularly among people with mild disease who may add to identified cases to represent how much COVID-19 is within the community and are an important group to help estimate true burden of disease.

Therefore, [LHD] and CDPH are partnering with [HEALTHCARE FACILITY NAME] to conduct sentinel community surveillance for COVID-19 in coordination with other sites throughout the state. Using a standardized protocol, this surveillance will involve identifying a limited number of patients with mild illness per week (e.g. 50/week), collecting key demographic, occupation, exposure, and clinical data on those patients, and collecting and sending respiratory specimens to public health laboratories for SARS-CoV-2 and other respiratory virus testing.

This sentinel community surveillance system will allow for the collection of standardized data on COVID-19 prevalence among those with mild illness throughout California, while conserving most resources for patients with severe illness. Most critically, data from this surveillance will guide decisions on the effectiveness of implemented mitigation strategies (e.g., shelter-in-place orders) and how public health can most effectively utilize mitigation and containment strategies moving forward.

Our agency looks forward to partnering with [HEALTHCARE FACILITY NAME] to conduct this surveillance to assess and track COVID-19 and other respiratory viruses in [COUNTY], in order to protect our community's health. Please feel free to contact me with any questions.

[SIGNATURE]

[OPTIONAL: ADD LETTERHEAD]

[LOCAL HEALTH DEPARTMENT NAME] & California Department of Public Health
COVID-19 Community & Sentinel Surveillance

Project Protocols and Reporting Requirements

[HEALTHCARE FACILITY NAME] is partnering with the [LOCAL HEALTH DEPARTMENT] and the California Department of Public Health to conduct community and sentinel surveillance for COVID-19 and other respiratory pathogens. As part of this public health surveillance, healthcare providers will be asked to pre-screen patients for eligibility in this surveillance project, administer a project-specific patient questionnaire, and collect and submit respiratory specimens for SARS-CoV-2 and other respiratory virus testing If you have any questions about this surveillance project, please contact [APPROPRIATE EMAIL ADDRESS].

1. Supplies Needed
   - Personal protective equipment (PPE) necessary for collection of SARS-CoV-2 respiratory specimens – [ADD SITE SPECIFIC REQUIREMENTS]
   - Patient pre-screening questionnaires and patient intake forms – [ADD DETAILS ON HOW THESE CAN BE ACCESSED]
   - Specimen collection materials – [ADD SITE SPECIFIC MATERIALS]

2. Patient Eligibility
   - To determine patient eligibility, patients should be pre-screened to make sure they meet the following criteria:

     - Visit one of the selected testing sites, and
     - Present with mild or asymptomatic illness. Asymptomatic patients should not make up >20% of county patient sample. Mildly ill patients should preferably meet the clinical criteria below. Listed symptoms should be <u>new or worsening</u> (i.e., exclude patients who chronically have these symptoms due to long-term comorbid conditions):
       - <u>At least two</u> of the following symptoms (if patient is non-verbal [e.g. infant] <u>at least one</u> of the following is sufficient):
         - Fever (measured or subjective)
         - Cough
         - Shortness of breath or difficulty breathing
         - Chills or rigors
         - Myalgia
         - Headache
         - Sore throat
         - New olfactory or taste disorder(s)
         - Congestion or runny nose
         - Nausea or vomiting
         - Diarrhea
         - Fatigue
     - Have been notified about SARS-CoV-2 either verbally or in writing

3. Patient Pre-screening and Data Collection

[OPTIONAL: ADD LETTERHEAD]

- Patients should be pre-screened and, if eligible, this questionnaire should be completed and submitted.
- Eligible patients should complete the self-administered patient intake form
- If a patient is eligible, staff should ask the patient all questions on the patient intake form
- [PROVIDE DETAILS ON HOW TO ACCESS FORMS]
- For all eligible patients, the the patient intake form should be submitted [PROVIDE DETAILS ON WHO TO SUBMIT TO AT HEALTHCARE FACILITY]

4. Specimen Collection and Handling
   - For eligible patients, a respiratory specimen should be collected [DESCRIBE RELEVANT PROCEDURES INCLUDING TYPE OF SPECIMEN]
   - Although the specimen will be tested for multiple pathogens, only one respiratory specimen is needed.
   - Specimens should be [PROVIDE DETAILS ON HOW TO HANDLE SPECIMENS AFTER COLLECTED]

5. Provider Checklist
   - For each patient pre-screened for this surveillance and identified as eligible, please submit:

     ❑ Complete patient intake form
     ❑ One respiratory specimen

6. Results and Reporting
   - Specimens will be tested for SARS-CoV-2 at [INDICATE LAB]. The ordering provider will be notified of positive SARS-CoV-2 results within [TURNAROUND TIME].
   - Specimens will be tested for other respiratory viruses at [INDICATE LAB]. The ordering provider will be notified of positive results for other respiratory viruses within [TURNAROUND TIME].

7. Healthcare Facility-level Data
   - As part of participation in this surveillance project, healthcare facility sites are also being asked to submit weekly facility-level data. The objective of this data request is to gather the minimum data needed to provide a crude estimate of underlying burden of COVID-19 cases in each participating facility/jurisdiction.
   - **Please note that if collection, reporting, and transmission of these data is challenging, this piece of the project can wait until specimen and other data collection procedures have been established and refined.** *CDPH will host a training call with CDC* partners *on this piece to answer questions about data collection and transmission.*
   - If possible, please provide values across all ages, and stratified by the following age groups: 0-4 years, 5-17 years, 18-49 years, 50-64 years, and ≥65 years.
   - Table 1 below describes the data request from each participating site each week per CDC guidance.

TABLE 1: FACILITY-LEVEL DATA

Values	All ages	0-4 years	5-17 years	18-49 years	50-64 years	65+ years
Number of ILI visits or unique ILI patients seen at facility, per week						
Number of total visits or unique patients seen at facility, per week						

Commented [CG2]: Sites can choose which of these two options works best for their routine procedures

Commented [CG3]: Please note that once specimens are received at VRDL for SARS-COV-2 testing, the turnaround time is 2 days

Commented [CG4]: Please note that once specimens are received at VRDL for RVP, the turnaround time is 2-3 weeks

[OPTIONAL: ADD LETTERHEAD]

8. Submission of data and specimens to [LOCAL HEALTH DEPARTMENT]
    - [PROVIDE DETAILS ON HOW AND HOW OFTEN THE HEALTHCARE FACILITY WILL SUBMIT PATIENT DATA TO THE LHD]
    - [PROVIDE DETAILS ON HOW AND HOW OFTEN THE HEALTHCARE FACILITY WILL SUBMIT SPECIMENS INCLUDING FREQUENCY, ADDRESS, AND HANDLING, STORAGE, AND SHIPPING DETAILS]
    - Every [DAY/WEEK], healthcare facilities are expected to submit the following for all eligible patients:

        ❑ Complete patient intake form
        ❑ One respiratory specimen

    - Every week, healthcare facilities are expected to submit facility-level data by [PROVIDE DETAILS ON HOW TO SUBMIT DATA TO THE LHD]

        ❑ Complete TABLE 1: FACILITY-LEVEL DATA

9. Additional Information
    - For more information of COVID-19 please visit [LHD COVID-19 WEBPAGE] or https://www.covid19.ca.gov/
    - To learn more about similar COVID-19 sentinel community surveillance projects, reference:
        (1) Zwald ML, Lin W, Sondermeyer Cooksey GL, et al. Rapid Sentinel Surveillance for COVID-19 — Santa Clara County, California, March 2020. MMWR Morb Mortal Wkly Rep. ePub: 3 April 2020. DOI: http://dx.doi.org/10.15585/mmwr.mm6914e3
        (2) Spellberg B, Haddix M, Lee R, et al. Community prevalence of SARS-CoV-2 among patients with influenzalike illnesses presenting to a Los Angeles medical center in March 2020. JAMA 2020
    - For questions regarding this surveillance, please contact [PROVIDE INFO]

Thank you for partnering with [LOCAL HEALTH DEPARTMENT] to conduct this important surveillance project to assess and track COVID-19 and other respiratory viruses in [COUNTY] in order to protect our community's health.