

STATE OF CALIFORNIA - DEPARTMENT OF GENERAL SERVICES

STANDARD AGREEMENT

STD 213 (Rev. 04/2020)

AGREEMENT NUMBER 20-10792	PURCHASING AUTHORITY NUMBER (If Applicable)
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1. This Agreement is entered into between the Contracting Agency and the Contractor named below:

CONTRACTING AGENCY NAME
California Department of Public Health

CONTRACTOR NAME
Color Genomics, Inc.

2. The term of this Agreement is:

START DATE
11/24/2020

THROUGH END DATE
4/30/2021

3. The maximum amount of this Agreement is:
\$50,000,000.00
Fifty Million Dollars and Zero Cents

4. The parties agree to comply with the terms and conditions of the following exhibits, which are by this reference made a part of the Agreement.

Exhibits	Title	Pages
Exhibit A	Scope of Work	5
Exhibit B	Budget Detail & Provisions	3
	Attachment 1 Budget Detail	2
+ - Exhibit C	General Terms & Conditions	04/2017
+ - Exhibit D	Special Terms & Conditions	7
+ - Exhibit E	HIPAA/BAA	14
+ - Exhibit F	FEMA Provisions	5

Items shown with an asterisk (*), are hereby incorporated by reference and made part of this agreement as if attached hereto.

These documents can be viewed at <https://www.dgs.ca.gov/OLS/Resources>

IN WITNESS WHEREOF, THIS AGREEMENT HAS BEEN EXECUTED BY THE PARTIES HERETO.

CONTRACTOR

CONTRACTOR NAME (if other than an individual, state whether a corporation, partnership, etc.)
Color Genomics, Inc.

CONTRACTOR BUSINESS ADDRESS 831 Mitten Rd, Suite 300	CITY Burlingame	STATE CA	ZIP 94010
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PRINTED NAME OF PERSON SIGNING Caroline Savello	TITLE Chief Commercial Officer
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CONTRACTOR AUTHORIZED SIGNATURE Caroline Savello	DATE SIGNED Digitally signed by Caroline Savello Date: 2020.12.01 19:11:23 -08'00'
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STATE OF CALIFORNIA - DEPARTMENT OF GENERAL SERVICES

STANDARD AGREEMENT

STD 213 (Rev. 04/2020)

AGREEMENT NUMBER 20-10792	PURCHASING AUTHORITY NUMBER (If Applicable)
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STATE OF CALIFORNIA

CONTRACTING AGENCY NAME

California Department of Public Health

CONTRACTING AGENCY ADDRESS

1615 Capitol Ave

CITY

Sacramento

STATE

CA

ZIP

95814

PRINTED NAME OF PERSON SIGNING

Tim Bow

TITLE

Procurement Officer

CONTRACTING AGENCY AUTHORIZED SIGNATURE

Timothy Bow

Digitally signed by Timothy Bow
Date: 2020.12.02 07:24:45 -08'00'

DATE SIGNED

CALIFORNIA DEPARTMENT OF GENERAL SERVICES APPROVAL

EXEMPTION (If Applicable)

PCC 1102

Executive Order N-25-20-COVID19

**Exhibit A
Scope of Work**

1. Service Overview

Contractor agrees to provide to the California Department of Public Health (CDPH) the services described herein.

Color will provide services to support broadly distributed COVID-19 testing efforts across the State of California by managing the total life cycle of community sample collection sites, providing institutional data integrations, and establishing consistent reporting across sample collection efforts.

This agreement may be amended for up to an additional 6 months by mutual agreement. CDPH shall provide Color with the intent to renewal within 30 days prior the expiration of the contract.

2. Service Location

The services shall be performed at location proposed by the Contractor and agreed upon by the State.

3. Service Hours

The services shall be provided as needed as determined by CDPH.

4. Project Representatives

A. The project representatives during the term of this agreement will be:

California Department of Public Health Sabel Davis Telephone: 916-650-0134 Fax: N/A E-mail: Sabel.Davis@cdph.ca.gov	Color Genomics, Inc. Caroline Savello Telephone: 650-651-7116 Fax: N/A E-mail: caroline@color.com
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B. Direct all inquiries to:

California Department of Public Health Attention: Sabel Davis Mail Station Code 1804 1616 Capitol Ave, Ste 74.2.11 Sacramento, CA 95814 Telephone: 916-650-0134 Fax: N/A E-mail: Sabel.Davis@cdph.ca.gov	Color Genomics, Inc. Attention: Caroline Savello 831 Mitten Rd, Suite 100 Burlingame, CA 94010 Telephone: 650-651-7116 Fax: N/A E-mail: caroline@color.com
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Exhibit A
Scope of Work

C. All payments from CDPH to the Contractor; shall be sent to the following address:

Remittance Address
Contractor: [Color Genomics, Inc.]
Attention "Cashier":
831 Mitten Rd, Suite 100
Burlingame, CA 94010
650-651-7116
caroline@color.com

D. Either party may make changes to the information above by giving written notice to the other party. Said changes shall not require an amendment to this agreement.

5. Services to be Performed

A. Community Sample Collection Services

1. Account management
 - Provide support through Color's dedicated California account management team. Account managers available for specialized online training.
 - Real-time support available 7 days/week via email and 6am to 5pm M-F via dedicated 1-800-number.
2. Site planning, onboarding & ongoing support
 - Define organizations' approaches to sample collection (e.g., frequency, timing, modality) and preparing logistics. Training available through office hours, support videos, website and robust documentation
 - Offer logistics and infrastructure planning, documentation of equipment requirements (technology list with procurement details), and guidance on staffing
 - Provide site setup best practices and materials, including QR codes for pre-registration, and signage design for testing events in multiple languages
 - Provide ongoing technical support & troubleshooting
3. Collection kit onsite inventory management

Exhibit A Scope of Work

- Train sites on kit inventory management & ordering portal
 - Provide inventory management tool to track kits & trigger ordering based on utilization rates and planned collections
 - Ordering portal to allow for direct requests for sample collection kits and shipback materials by sites
4. Courier and shipping management
- Train site teams on logistics management, batch shipping and electronic manifest tools
 - Provide batch shipping and electronic manifest tools to allow for tracking samples from site to lab
 - Integrate with State-contracted couriers and shipment companies for tracking and reporting
5. Results management configurations
- Provide aggregate results dashboard at the organization level, with ability to drill down by site
6. Program strategy
- Support engagement with potential sites to demonstrate system capabilities and operational requirements
 - Report on process and results metrics
 - Share best practices, innovative solutions across system, and new opportunities for expanding access
 - Create hub/spoke model of site management for participant registration, site setup, and resulting
7. Advanced participant registration configurations
- Schedule participant appointment blocks (with built in cancellation and rescheduling)
 - Provide pre-registration workflows using eligibility files to reduce burden of on-site data collection (e.g., for SNFs and congregate living facilities)
 - Provide participant account creation software modules to support repeat testing protocols and compliance tracking
8. Advanced results management configurations
- Provide individual-level PHI reporting to organizations (e.g., employers, schools, congregate living facilities) to monitor compliance and positivity rates to manage safety of workforce, students, or residents
 - Digital HIPAA authorization integrated with registration flow to allow release of PHI data to institutions
9. Onsite oversight and staffing

Exhibit A Scope of Work

- At the State's request, provide onsite sample collection oversight, training, and staffing from trained non-clinical or clinical staff

B. Data Integration Services

1. Implement custom HL7 integration for ordering and resulting with OptumServe to shift testing to VBL at launch
2. Establish a limited set of options for key organizations with special needs (e.g., CDCR, DHS, LAUSD) for bidirectional integration interfaces for ordering and resulting:
 - HL7 or equivalent feeds
 - Ongoing maintenance and troubleshooting support
3. Provide integration mechanism for one-way sharing of results data with entities responsible for downstream processes (e.g., billing, contact tracing, genetic sequencing, etc.)

C. Reporting Services

1. Provide reporting on sample collection through reporting:
 - Filtering by date range and collection site
 - Tracking sample/result status by date: collected, shipped, received, accessioned, released, and opened
 - Results, including daily and 7-day average positivity rates
 - Collection to accessioning and report release to open durations
 - Breakdown by zip code, race/ethnicity, collection site

D. Provide comprehensive reporting on collection site characteristics, status in on-boarding process, and forecasting for volumes

E. Provide automated data feeds on all sample collection and test processing data to CDPH

6. Implementation Responsibilities

State/CDPH:

- Identifies and prioritizes sites based on needs/goals
- Approves organizations to participate in program
- Secures MOUs and provides guidelines for participation (estimated volumes, duration, number of sites)
- Approves provision of sample collection kits
- Provides each organization's point of contact
- Designates organization/site as requiring standard or specialized support services

Exhibit A Scope of Work

Contractor/Color:

- Reaches out to approved organizations for planning and onboarding
- Assigns account manager from dedicated team
- Provides setup webform, tools, documentation, training, and support email/phone number
- Launches site and manages ongoing needs, coordinating with site's trained clinical or non-clinical staff
- Provides onsite staff support or oversight (as needed)
- Supports advanced participant registration configurations
- Supports advanced results management configurations

Collection sites:

- Provides location, necessary equipment and hardware, PPE and other consumables
- Selects and manages staff for participant registration, sample collection, site set-up/take-down, security/safety
- Prints signage and materials
- Manages materials storage, waste disposal
- Maintains all required insurance and permits

Exhibit B
Budget Detail and Payment Provisions

1. Invoicing and Payment

- A. In no event shall the Contractor request reimbursement from the State for obligations entered into or for costs incurred prior to the commencement date or after the expiration of this Agreement.
- B. For services satisfactorily rendered, and upon receipt and approval of the invoices, the State agrees to compensate the Contractor for actual expenditures incurred in accordance with the amounts found in Exhibit B Attachment 1: Budget Detail.
- C. Invoices shall include the Agreement Number and shall be submitted in triplicate not more frequently than monthly in arrears to:

Phebe Lapinig
California Department of Public Health
Emergency Preparedness Office
MS 7002
1615 Capitol Ave, 73.373
Sacramento, CA 95814

- D. Invoice shall:
 - 1) Be prepared on Contractor letterhead. If invoices are not on produced letterhead invoices must be signed by an authorized official, employee or agent certifying that the expenditures claimed represent activities performed and are in accordance with Exhibit A.
 - 2) Invoices must be submitted to CDPH either electronically or in hard copies.
 - 3) Identify the billing and/or performance period covered by the invoice.
 - 4) Itemize costs for the billing period in the same or greater level of detail as indicated in this agreement. Subject to the terms of this agreement, reimbursement may only be sought for those costs and/or cost categories expressly identified as allowable in this agreement and approved by CDPH.

E. Amounts Payable

The amounts payable under this agreement shall not exceed: \$50,000,000.00

2. Budget Contingency Clause

- A. It is mutually agreed that if the Budget Act of the current year and/or any subsequent years covered under this Agreement does not appropriate sufficient funds for the program, this Agreement shall be of no further force and effect. In this event, the State shall have no liability to pay any funds whatsoever to Contractor or to furnish any other considerations under this Agreement and Contractor shall not be obligated to perform any provisions of this Agreement.
- B. If funding for any fiscal year is reduced or deleted by the Budget Act for purposes of this program, the State shall have the option to either cancel this Agreement with no liability

Exhibit B
Budget Detail and Payment Provisions

occurring to the State, or offer an agreement amendment to Contractor to reflect the reduced amount.

3. Prompt Payment Clause

Payment will be made in accordance with, and within the time specified in, Government Code Chapter 4.5, commencing with Section 927.

4. Timely Submission of Final Invoice

A. A final undisputed invoice shall be submitted for payment no more than *thirty (30)* calendar days following the expiration or termination date of this agreement, unless a later or alternate deadline is agreed to in writing by the program contract manager. Said invoice should be clearly marked "Final Invoice", indicating that all payment obligations of the State under this agreement have ceased and that no further payments are due or outstanding. The State may, at its discretion, choose not to honor any delinquent final invoice if the Contractor fails to obtain prior written State approval of an alternate final invoice submission deadline.

5. Expense Allowability / Fiscal Documentation

- A. Invoices, received from the Contractor and accepted for payment by the State, shall not be deemed evidence of allowable agreement costs.
- B. Contractor shall maintain for review and audit and supply to CDPH upon request, adequate documentation of all expenses claimed pursuant to this agreement to permit a determination of expense allowability.
- C. If the allowability of an expense cannot be determined by the State because invoice detail, fiscal records, or backup documentation is nonexistent or inadequate according to generally accepted accounting principles or practices, all questionable costs may be disallowed and payment may be withheld by the State. Upon receipt of adequate documentation supporting a disallowed or questionable expense, reimbursement may resume for the amount substantiated and deemed allowable.

6. Recovery of Overpayments

- A. Contractor agrees that claims based upon the terms of this agreement or an audit finding and/or an audit finding that is appealed and upheld, will be recovered by the State by one of the following options:
 - 1) Contractor's remittance to the State of the full amount of the audit exception within 30 days following the State's request for repayment;
 - 2) A repayment schedule agreeable between the State and the Contractor.
- B. The State reserves the right to select which option as indicated above in paragraph A will be employed and the Contractor will be notified by the State in writing of the claim procedure to be utilized.

Exhibit B
Budget Detail and Payment Provisions

- C. Interest on the unpaid balance of the audit finding or debt will accrue at a rate equal to the monthly average of the rate received on investments in the Pooled Money Investment Fund commencing on the date that an audit or examination finding is mailed to the Contractor, beginning 30 days after Contractor's receipt of the State's demand for repayment.
- D. If the Contractor has filed a valid appeal regarding the report of audit findings, recovery of the overpayments will be deferred until a final administrative decision on the appeal has been reached. If the Contractor loses the final administrative appeal, Contractor shall repay, to the State, the over-claimed or disallowed expenses, plus accrued interest. Interest accrues from the Contractor's first receipt of State's notice requesting reimbursement of questioned audit costs or disallowed expenses.

Exhibit B Attachment 1: Budget Detail

Community Sample Collection Infrastructure

Pricing tiers set by cumulative samples collected through Color's services. The State intends to collect 9 million samples with Color over 6-month term

Service by cumulative sample volume	Fee
First 2 million samples collected	\$8.15/sample collected
Subsequent 2 million samples collected	\$7.00/sample collected
Additional samples collected beyond initial 4 million	\$4.75/sample collected

Data Integration Services

Service	Fee
Ordering & Results Feed integration (HL7 or equivalent bi-directional API feeds) (e.g., OptumServe, CDCR, DSH, LAUSD)	\$18,000/integration one-time fee + \$500/month maintenance fee
Results Feed integration (e.g., billing, contact tracing, genetic sequencing)	\$18,000/integration one-time fee

- *Color is waiving two integration costs already incurred: OptumServe HL7 integration & Sutherland Group billing integration*
- *These services will be on an as-needed basis. CDPH will determine whether fees will be paid by CDPH or by testing institution (e.g., school district, clinic, State agency)*

Reporting Services

Service	Fee
State reporting sample collection dashboard administration & creation of automated data feed, including monitoring site contact characteristics, onboarding status, and volume forecasting	\$12,600 one-time fee
Customized reporting dashboard administration & creation of automated data feed for organizations with multiple sites (e.g. local health jurisdictions, school districts, etc.)	\$1k/month per custom dashboard

- *These services will be on an as-needed basis. CDPH will determine whether fees will be paid by CDPH or by testing institution (e.g., school district, clinic, State agency)*

Optional On-Site Staffing Services

Service	Fee
Onsite staffing of trained individuals to oversee or support community-based sample collection. Includes PPE and travel within 2 hours of California metro area	\$505/staff member daily rate

- *These services will be on an as-needed basis. CDPH will determine whether fees will be paid by CDPH or by testing institution (e.g., school district, clinic, State agency)*
- *Any staffing request beyond 2 hours drive outside of California metro area will be reimbursed at prevailing IRS reimbursement rate per mile (at time of execution, \$0.575/mile)*

Exhibit D
Special Terms and Conditions [Rev 06-2019]

(Applicable to consultant and personal service contracts)

The provisions herein apply to this Agreement unless the provisions are removed by reference, or superseded by an alternate provision appearing in Exhibit E of this Agreement.

Index

1. Cancellation
2. Intellectual Property Rights
3. Confidentiality of Information
4. Dispute Resolution Process
5. Excise Taxes
6. Indemnity; Limitation of Liability

Exhibit D Special Terms and Conditions

1. Cancellation

- A. This agreement may be cancelled by CDPH **without cause** upon 30 calendar days advance written notice to the Contractor.
- B. CDPH reserves the right to cancel or terminate this agreement immediately upon written notice for Contractor's breach of the Agreement and failure to cure such breach within the time period specified by CDPH to CDPH's reasonable satisfaction. The Contractor may submit a written request to terminate this agreement only if CDPH substantially fails to perform its responsibilities as provided herein.
- C. The term "for cause" shall mean that the Contractor fails to meet the terms, conditions, and/or responsibilities of this agreement.
- D. Agreement cancellation or termination shall be effective as of the date indicated in CDPH's notification to the Contractor. The notice shall stipulate any final performance, invoicing or payment requirements.
- E. Upon receipt of a notice of cancellation or termination, the Contractor shall take immediate steps to stop performance and to cancel or reduce subsequent agreement costs.
- F. In the event of early cancellation or termination, the Contractor shall be entitled to compensation for services performed satisfactorily under this agreement and expenses incurred up to the date of cancellation and any non-cancelable obligations incurred in support of this agreement.

2. Intellectual Property Rights

A. Ownership

- 1)
- 2) CDPH does not require any license of any intellectual property of Contractor ("**Color Intellectual Property**") to receive the Color Services. If, in the future, CDPH requires a license of Color Intellectual Property to receive the Color Services, Contractor shall grant to CDPH a non-exclusive, worldwide, non-transferable, non-sublicensable, royalty-free license during the term of the Agreement to use Color Intellectual Property to the extent necessary for CDPH to receive the benefits of the Color Services. Such license shall terminate automatically upon termination of this Agreement.
- 3) For the purposes of this Agreement, Intellectual Property means recognized protectable rights and interest such as: patents, (whether or not issued) copyrights, trademarks, service marks, applications for any of the foregoing, inventions, trade secrets, trade dress, logos, insignia, color combinations, slogans, moral rights, right of publicity, author's rights, contract and licensing rights, works, mask works, industrial design rights, rights of priority, know how, design flows, methodologies, devices, business processes, developments, innovations, good will and all other legal rights protecting intangible proprietary information as may exist now and/or here after come into existence, and all renewals and extensions, regardless of whether those rights arise under the laws of the United States, or any other state, country or jurisdiction.
- 4) For the purposes of the definition of Intellectual Property, "works" means all literary works, writings and printed matter including the medium by which they are recorded or reproduced, photographs, art work, pictorial and graphic representations and works of a similar nature, film, motion pictures, digital images, animation cells, and other audiovisual works including positives and negatives thereof, sound recordings, tapes, educational materials, interactive videos and any other materials or products created, produced, conceptualized and fixed in a tangible medium of expression. It

includes preliminary and final products and any materials and information developed for the purposes of producing those final products. Works does not include articles submitted to peer review or reference journals or independent research projects.

- 5) In the performance of this Agreement, Contractor will exercise and utilize certain of its Intellectual Property in existence prior to the effective date of this Agreement. In addition, under this Agreement, Contractor may access and utilize certain of CDPH's Intellectual Property in existence prior to the effective date of this Agreement. Except as otherwise set forth herein, Contractor shall not use any of CDPH's Intellectual Property now existing or hereafter existing for any purposes without the prior written permission of CDPH. **Except as otherwise set forth herein, neither the Contractor nor CDPH shall give any ownership interest in or rights to its Intellectual Property to the other Party.** If during the term of this Agreement, Contractor accesses any third-party Intellectual Property that is licensed to CDPH, Contractor agrees to abide by all license and confidentiality restrictions applicable to CDPH in the third-party's license agreement.
- 6) Contractor further agrees to assist and cooperate with CDPH in all reasonable respects, and execute all documents and, subject to reasonable availability, give testimony and take all further acts reasonably necessary to acquire, transfer, maintain, and enforce CDPH's Intellectual Property rights and interests.

B. Retained Rights / License Rights

- 1) Contractor shall retain title to all of its Intellectual Property..
- 2) Nothing in this provision shall restrict, limit, or otherwise prevent Contractor from using any ideas, concepts, know-how, methodology or techniques related to its performance under this Agreement, provided that Contractor's use does not infringe the patent, copyright, trademark rights, license or other Intellectual Property rights of CDPH or third party, or result in a breach or default of any provisions of this Exhibit or result in a breach of any provisions of law relating to confidentiality.

C. Copyright

- 1) Contractor agrees that for purposes of copyright law, all works [as defined in Section a, subparagraph (2)(a)] of authorship made by or on behalf of Contractor in connection with Contractor's performance of this Agreement shall be deemed "works made for hire". Contractor further agrees that the work of each person utilized by Contractor in connection with the performance of this Agreement will be a "work made for hire," whether that person is an employee of Contractor or that person has entered into an agreement with Contractor to perform the work. Contractor shall enter into a written agreement with any such person that: (i) all work performed for Contractor shall be deemed a "work made for hire" under the Copyright Act and (ii) that person shall assign all right, title, and interest to CDPH to any work product made, conceived, derived from, or reduced to practice by Contractor or CDPH and which result directly or indirectly from this Agreement.
- 2) All materials, including, but not limited to, visual works or text, reproduced or distributed pursuant to this Agreement that include Intellectual Property made, conceived, derived from, or reduced to practice by Contractor or CDPH and which result directly or indirectly from this Agreement, shall include CDPH's notice of copyright, which shall read in 3mm or larger typeface: "© [Enter Current Year e.g., 2007, etc.], California Department of Public Health. This material may not be reproduced or disseminated without prior written permission from the California Department of Public Health." This notice should be placed prominently on the materials and set apart from other matter on the page where it appears. Audio productions shall contain a similar audio notice of copyright.

D. Patent Rights

E. [Intentionally left blank]. Third-Party Intellectual Property

Except as provided herein, Contractor agrees that its performance of this Agreement shall not be dependent upon or include any Intellectual Property of Contractor or third party without first: (i)

obtaining CDPH's prior written approval; and (ii) granting to or obtaining for CDPH, without additional compensation, a license, as described in Paragraph b of this provision, for any of Contractor's or third-party's Intellectual Property in existence prior to the effective date of this Agreement. If such a license upon the these terms is unattainable, and CDPH determines that the Intellectual Property should be included in or is required for Contractor's performance of this Agreement, Contractor shall obtain a license under terms acceptable to CDPH.

F. Warranties

- 1) Contractor represents and warrants that:
 - a. It is free to enter into and fully perform this Agreement.
 - b. It has secured and will secure all rights and licenses necessary for its performance of this Agreement.
 - c. Neither Contractor's performance of this Agreement, nor the exercise by either Party of the rights granted in this Agreement, nor any use, reproduction, manufacture, sale, offer to sell, import, export, modification, public and private display/performance, distribution, and disposition of the Intellectual Property made, conceived, derived from, or reduced to practice by Contractor or CDPH and which result directly or indirectly from this Agreement will infringe upon or violate any Intellectual Property right, non-disclosure obligation, or other proprietary right or interest of any third-party or entity now existing under the laws of, or hereafter existing or issued by, any state, the United States, or any foreign country. There is currently no actual or threatened claim by any such third party based on an alleged violation of any such right by Contractor.
 - d. Neither Contractor's performance nor any part of its performance will violate the right of privacy of, or constitute a libel or slander against any person or entity.
 - e. It has secured or will secure, as may be necessary, all rights and licenses necessary for Intellectual Property including, but not limited to, consents, waivers or releases from all authors of music or performances used, and talent (radio, television and motion picture talent), owners of any interest in and to real estate, sites, locations, property or props that may be used or shown.
 - f. It has not granted and shall not grant to any person or entity any right that would or might derogate, encumber, or interfere with any of the rights granted to CDPH in this Agreement.
 - g. It has appropriate systems and controls in place to ensure that state funds will not be used in the performance of this Agreement for the acquisition, operation or maintenance of computer software in violation of copyright laws.
 - h. It has no knowledge of any outstanding claims, licenses or other charges, liens, or encumbrances of any kind or nature whatsoever that could affect in any way Contractor's performance of this Agreement.
- 2) CDPH MAKES NO WARRANTY THAT THE INTELLECTUAL PROPERTY RESULTING FROM THIS AGREEMENT DOES NOT INFRINGE UPON ANY PATENT, TRADEMARK, COPYRIGHT OR THE LIKE, NOW EXISTING OR SUBSEQUENTLY ISSUED.

G. Intellectual Property Indemnity

- 1) Contractor shall indemnify, defend and hold harmless CDPH and its licensees and assignees, and its officers, directors, employees, agents, representatives, successors, and users of its products, ("Indemnitees") from and against all claims, actions, damages, losses, liabilities (or actions or proceedings with respect to any thereof), whether or not rightful, arising from any and all actions or claims by any third party or expenses related thereto (including, but not limited to, all legal expenses, court costs, and attorney's fees incurred in investigating, preparing, serving as a witness in, or defending against, any such claim, action, or proceeding, commenced or threatened) to which

any of the Indemnitees may be subject, whether or not Contractor is a party to any pending or threatened litigation, which arise out of or are related to (i) the incorrectness or breach of any of the representations, warranties, covenants or agreements of Contractor pertaining to Intellectual Property; or (ii) any Intellectual Property infringement, or any other type of actual or alleged infringement claim, arising out of CDPH's use, reproduction, manufacture, sale, offer to sell, distribution, import, export, modification, public and private performance/display, license, and disposition of the Intellectual Property made, conceived, derived from, or reduced to practice by Contractor or CDPH and which result directly or indirectly from this Agreement. This indemnity obligation shall apply irrespective of whether the infringement claim is based on a patent, trademark or copyright registration that issued after the effective date of this Agreement. CDPH reserves the right to participate in , any such infringement action brought against CDPH.

- 2) Should any Intellectual Property licensed by the Contractor to CDPH under this Agreement become the subject of an Intellectual Property infringement claim, Contractor will exercise its authority reasonably and in good faith to preserve CDPH's right to use the licensed Intellectual Property in accordance with this Agreement at no expense to CDPH. CDPH shall have the right to monitor and appear through its own counsel (at Contractor's expense) in any such claim or action. In the defense or settlement of the claim, Contractor may obtain the right for CDPH to continue using the licensed Intellectual Property; or, replace or modify the licensed Intellectual Property so that the replaced or modified Intellectual Property becomes non-infringing provided that such replacement or modification is functionally equivalent to the original licensed Intellectual Property..
- 3) Contractor agrees that damages alone would be inadequate to compensate CDPH for breach of any term of this Intellectual Property Exhibit by Contractor. Contractor acknowledges CDPH would suffer irreparable harm in the event of such breach and agrees CDPH shall be entitled to obtain equitable relief, including without limitation an injunction, from a court of competent jurisdiction, without restriction or limitation of any other rights and remedies available at law or in equity.

H. Federal Funding

In any agreement funded in whole or in part by the federal government, CDPH may acquire and maintain the Intellectual Property rights, title, and ownership, which results directly or indirectly from the Agreement; except as provided in 37 Code of Federal Regulations part 401.14; however, the federal government shall have a non-exclusive, nontransferable, irrevocable, paid-up license throughout the world to use, duplicate, or dispose of such Intellectual Property throughout the world in any manner for governmental purposes and to have and permit others to do so.

I. Survival

The provisions set forth herein shall survive any termination or expiration of this Agreement or any project schedule.

3. Confidentiality of Information

- A. The Contractor and its employees, agents, or subcontractors shall protect from unauthorized disclosure names and other identifying information concerning persons either receiving services pursuant to this Agreement or persons whose names or identifying information become available or are disclosed to the Contractor, its employees, agents, or subcontractors as a result of services performed under this Agreement, except for statistical information not identifying any such person.
- B. The Contractor and its employees, agents, or subcontractors shall not use such identifying information for any purpose other than carrying out the Contractor's obligations under this Agreement or as required by law. As permitted by law, Color may use such identifying information for Color's internal quality assurance/improvement purposes.
- C. The Contractor and its employees, agents, or subcontractors shall promptly transmit to the CDPH Program Contract Manager all requests for disclosure of such identifying information not emanating from the client or person.

- D. The Contractor shall not disclose, except as otherwise specifically permitted by this Agreement or authorized by the client, any such identifying information to anyone other than CDPH without prior written authorization from the CDPH Program Contract Manager, except if disclosure is required by State or Federal law.
- E. For purposes of this provision, identity shall include, but not be limited to name, identifying number, symbol, or other identifying particular assigned to the individual, such as finger or voice print or a photograph.
- F. As deemed applicable by CDPH, this provision may be supplemented by additional terms and conditions covering personal health information (PHI) or personal, sensitive, and/or confidential information (PSCI). Said terms and conditions will be outlined in one or more exhibits that will either be attached to this Agreement or incorporated into this Agreement by reference.

Exhibit D

Special Terms and Conditions

4. Dispute Resolution Process

A Contractor grievance exists whenever there is a dispute arising from CDPH's action in the administration of an agreement. If there is a dispute or grievance between the Contractor and CDPH, the Contractor must seek resolution using the procedure outlined below.

- A. The Contractor should first informally discuss the problem with the CDPH Program Contract Manager. If the problem cannot be resolved informally, the Contractor shall direct its grievance together with any evidence, in writing, to the program Branch Chief. The grievance shall state the issues in dispute, the legal authority or other basis for the Contractor's position and the remedy sought. The Branch Chief shall render a decision within ten (10) working days after receipt of the written grievance from the Contractor. The Branch Chief shall respond in writing to the Contractor indicating the decision and reasons therefore. If the Contractor disagrees with the Branch Chief's decision, the Contractor may appeal to the second level.
- B. When appealing to the second level the Contractor must prepare an appeal indicating the reasons for disagreement with the Branch Chief's decision. The Contractor shall include with the appeal a copy of the Contractor's original statement of dispute along with any supporting evidence and a copy of the Branch Chief's decision. The appeal shall be addressed to the Deputy Director of the division in which the branch is organized within ten (10) working days from receipt of the Branch Chief's decision. The Deputy Director of the division in which the branch is organized or his/her designee shall meet with the Contractor to review the issues raised. A written decision signed by the Deputy Director of the division in which the branch is organized or his/her designee shall be directed to the Contractor within twenty (20) working days of receipt of the Contractor's second level appeal. The decision rendered by the Deputy Director or his/her designee shall be the final administrative determination of the Department.
- C. Unless otherwise stipulated in writing by CDPH, all dispute, grievance and/or appeal correspondence shall be directed to the CDPH Program Contract Manager.
- D. There are organizational differences within CDPH's funding programs and the management levels identified in this dispute resolution provision may not apply in every contractual situation. When a grievance is received and organizational differences exist, the Contractor shall be notified in writing by the CDPH Program Contract Manager of the level, name, and/or title of the appropriate management official that is responsible for issuing a decision at a given level.

5. Excise Tax

The State of California is exempt from federal excise taxes, and no payment will be made for any taxes levied on employees' wages. The State will pay for any applicable State of California or local sales or use taxes on the services rendered or equipment or parts supplied pursuant to this Agreement. California may pay any applicable sales and use tax imposed by another state.

6. Indemnity; Limitation of Liability

- A. Except to the extent limited by applicable law, notwithstanding any other provision of the Agreement, in no event shall either party be liable, regardless of whether any claim is based on contract or tort, for any special, consequential, indirect or incidental damages, including, but not limited to, lost profits, arising out of or in connection with this Agreement or the services performed in connection with this Agreement. Except for either party's negligence or willful misconduct, each party's maximum liability for any damages arising under or in connection with this Agreement or the services performed in connection with this Agreement shall be capped at the greater of \$1,000,000 or the amount actually paid by CDPH to Contractor under this Agreement. These limitations shall not apply to CDPH's payment obligations to Contractor under the Agreement.

EXHIBIT E
HIPAA Business Associate Addendum

I. Scope of Addendum

- A.** The underlying contract (Agreement), to which this HIPAA Business Associate Addendum is attached to and made a part of, has been determined to constitute a business associate relationship under the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191 ("HIPAA"), the Health Information Technology for Economic and Clinical Health Act, Public Law 111-005 ("the HITECH Act"), 42 U.S.C. section 17921 et seq., and their implementing privacy and security regulations at 45 CFR Parts 160 and 164 ("the HIPAA regulations").
- B.** As set forth in the Agreement, Contractor, here and after, is a "Covered Entity" and "Business Associate" as defined under HIPAA. It is providing health care services to patients pursuant to the Agreement. As a Covered Entity, HIPAA and the California Confidentiality of Medical Information Act apply to Contractor.
- C.** As set forth in the Agreement, Contractor, here and after, is the Business Associate of CDPH acting on CDPH's behalf and provides services, arranges, performs or assists in the performance of functions or activities on behalf of CDPH and creates, receives, maintains, transmits, uses or discloses PHI and PI. CDPH and Business Associate are each a party to the Agreement and are collectively referred to as the "parties."
- D.** The purpose of this Addendum is to protect the privacy and security of the PHI and PI that may be created, received, maintained, transmitted, used or disclosed pursuant to the Agreement, and to comply with certain standards and requirements of HIPAA, the HITECH Act and the HIPAA regulations, including, but not limited to, the requirement that CDPH must enter into a contract containing specific requirements with Contractor prior to the disclosure of PHI to Contractor, as set forth in 45 CFR Parts 160 and 164 and the HITECH Act.
- E.** The terms used in this Addendum, but not otherwise defined, shall have the same meanings as those terms have in the HIPAA regulations. Any reference to statutory or regulatory language shall be to such language as in effect or as amended.

II. Definitions

- A.** Breach shall have the meaning given to such term under HIPAA, the HITECH Act, and the HIPAA regulations.
- B.** Business Associate shall have the meaning given to such term under HIPAA, the HITECH Act, and the HIPAA regulations.
- C.** Covered Entity shall have the meaning given to such term under HIPAA, the HITECH Act, and the HIPAA regulations.
- D.** Electronic Health Record shall have the meaning given to such term in the HITECH Act, including, but not limited to, 42 U.S.C section 17921 and implementing regulations.
- E.** Electronic Protected Health Information (ePHI) means individually identifiable health information transmitted by electronic media or maintained in electronic media, including but not limited to electronic media as set forth under 45 CFR part 160.103.
- F.** Individually Identifiable Health Information means health information, including demographic information collected from an individual, that is created or received by a health care provider, health plan, employer or health care clearinghouse, and relates to the past, present or future physical or mental health or

EXHIBIT E
HIPAA Business Associate Addendum

condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual, that identifies the individual or where there is a reasonable basis to believe the information can be used to identify the individual, as set forth under 45 CFR section 160.103.

- G.** Privacy Rule shall mean the HIPAA Regulation that is found at 45 CFR Parts 160 and 164.
- H.** Personal Information shall have the meaning given to such term in California Civil Code sections 1798.3 and 1798.29.
- I.** Protected Health Information means individually identifiable health information that is transmitted by electronic media, maintained in electronic media, or is transmitted or maintained in any other form or medium, as set forth under 45 CFR section 160.103.
- J.** Required by law, as set forth under 45 CFR part 164.103, means a mandate contained in law that compels an entity to make a use or disclosure of PHI that is enforceable in a court of law. This includes, but is not limited to, court orders and court-ordered warrants, subpoenas or summons issued by a court, grand jury, a governmental or tribal inspector general, or an administrative body authorized to require the production of information, and a civil or an authorized investigative demand. It also includes Medicare conditions of participation with respect to health care providers participating in the program, and statutes or regulations that require the production of information, including statutes or regulations that require such information if payment is sought under a government program providing public benefits.
- K.** Secretary means the Secretary of the U.S. Department of Health and Human Services ("HHS") or the Secretary's designee.
- L.** Security Incident means the attempted or successful unauthorized access, use, disclosure, modification, or destruction of PHI or PI, or confidential data that is essential to the ongoing operation of Color's organization and intended for internal use; or interference with system operations in an information system.
- M.** Security Rule shall mean the HIPAA regulation that is found at 45 CFR Parts 160 and 164.
- N.** Unsecured PHI shall have the meaning given to such term under the HITECH Act, 42 U.S.C. section 17932(h), any guidance issued pursuant to such Act and the HIPAA regulations.

III. Terms of Agreement

A. Permitted Uses and Disclosures of PHI by Color

Permitted Uses and Disclosures. Except as otherwise indicated in this Addendum, Color may use or disclose PHI only to perform functions, activities or services specified in the Agreement, for, or on behalf of CDPH, including contacting participants to arrange for testing and returning the results of testing to participants, provided that such use or disclosure would not violate the HIPAA regulations, if done by CDPH. Any such use or disclosure must, to the extent practicable, be limited to the limited data set, as defined in 45 CFR section 164.514(e)(2), or, if needed, to the minimum necessary to accomplish the intended purpose of such use or disclosure, in compliance with the HITECH Act and any guidance issued pursuant to such Act, and the HIPAA regulations.

1. ***Specific Use and Disclosure Provisions.*** Except as otherwise indicated in this Addendum, Color may:

EXHIBIT E
HIPAA Business Associate Addendum

- a. **Use and disclose for management and administration.** Use and disclose PHI for the proper management and administration of Color provided that such disclosures are required by law, or Color obtains reasonable assurances from the person to whom the information is disclosed that it will remain confidential and will be used or further disclosed only as required by law or for the purpose for which it was disclosed to the person, and the person notifies Color of any instances of which it is aware that the confidentiality of the information has been breached.
- b. **Provision of Data Aggregation Services.** Use PHI to provide data aggregation services to CDPH. Data aggregation means the combining of PHI created or received by Color on behalf of CDPH with PHI received by Color in its capacity as Business Associate of another covered entity, to permit data analyses that relate to the health care operations of CDPH.
- c. **De-identification of PHI.** Color may use PHI to create de-identified health information. Such data de-identification shall be performed in accordance with the California Health and Human Services Agency Data De-Identification Guidelines (Sept. 23, 2016), in consultation with CDPH. Color may use de-identified data for purposes of developing COVID-19-related products and services.

B. Prohibited Uses and Disclosures

1. Color shall not disclose PHI about an individual to a health plan for payment or health care operations purposes if the PHI pertains solely to a health care item or service for which the health care provider involved has been paid out of pocket in full by the individual and the individual requests such restriction, in accordance with 42 U.S.C. section 17935(a) and 45 CFR section 164.522(a).
2. Color shall not directly or indirectly receive remuneration in exchange for PHI, except with the prior written consent of CDPH and as permitted by 42 U.S.C. section 17935(d)(2).

C. Responsibilities of Color

Color agrees:

1. **Nondisclosure.** Not to use or disclose PHI other than as permitted or required by the Agreement or as required by law.
2. **Safeguards.** To implement administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of the PHI, including electronic PHI, that it creates, receives, maintains, uses or transmits on behalf of CDPH, in compliance with 45 CFR parts 164.308, 164.310 and 164.312, and to prevent use or disclosure of PHI other than as provided for by the Agreement. Color shall implement reasonable and appropriate policies and procedures to comply with the standards, implementation specifications and other requirements of 45 CFR part 164, subpart C, in compliance with 45 CFR part 164.316. Color shall develop and maintain a written information privacy and security program that includes administrative, technical and physical safeguards appropriate to the size and complexity of Color's operations and the nature and scope of its activities, and which incorporates the requirements of section 3, Security, below. Business Associate will make available to CDPH copies of its policies upon request.
3. **Security.** To take any and all steps necessary to ensure the continuous security of all computerized data systems containing PHI and/or PI, and to protect paper documents containing PHI and/or PI. These steps shall include, at a minimum:

EXHIBIT E
HIPAA Business Associate Addendum

- a. Complying with all of the data system security precautions listed in Attachment A, Business Associate Data Security Requirements;
- b. Achieving and maintaining compliance with the HIPAA Security Rule (45 CFR Parts 160 and 164), as necessary in conducting operations on behalf of CDPH under the Agreement;
- c. Providing a level and scope of security that is at least comparable to the level and scope of security established by the Office of Management and Budget in OMB Circular No. A-130, Appendix III - Security of Federal Automated Information Systems, which sets forth guidelines for automated information systems in Federal agencies; and
- d. In case of a conflict between any of the security standards contained in any of these enumerated sources of security standards, the most stringent shall apply. The most stringent means that safeguard which provides the highest level of protection to PHI from unauthorized disclosure. Further, Color must comply with changes to these standards that occur after the effective date of the Agreement.
- e. Color shall designate a Security Officer to oversee its data security program who shall be responsible for carrying out the requirements of this section and for communicating on security matters with CDPH.

D. *Mitigation of Harmful Effects.* To mitigate, to the extent practicable, any harmful effect that is known to Color of a use or disclosure of PHI by Color or its subcontractors in violation of the requirements of this Addendum.

E. *Color's Agents and Subcontractors.*

1. To enter into written agreements with any agents, including subcontractors and vendors, to whom Color provides PHI or PI received from or created or received by Color on behalf of CDPH, that impose the same restrictions and conditions on such agents, subcontractors and vendors that apply to Color with respect to such PHI and PI under this Addendum, and that comply with all applicable provisions of HIPAA, the HITECH Act and the HIPAA regulations.
2. In accordance with 45 CFR section 164.504(e)(1)(ii), upon Color's knowledge of a material breach or violation by its subcontractor of the agreement between Color and the subcontractor, Color shall:
 - a. Provide an opportunity for the subcontractor to cure the breach or end the violation and terminate the agreement if the subcontractor does not cure the breach or end the violation within the time specified by CDPH; or
 - b. Immediately terminate the agreement if the subcontractor has breached a material term of the agreement and cure is not possible.

F. *Availability of Information to CDPH and Individuals.* To provide access and information:

1. To provide access as CDPH may require, and in the time and manner designated by CDPH (upon reasonable notice and during Color's normal business hours) to PHI in a Designated Record Set, to CDPH (or, as directed by CDPH), to an Individual, in accordance with 45 CFR section 164.524. Designated Record Set means the group of records maintained for CDPH that includes medical, dental and billing records about individuals; enrollment, payment, claims adjudication, and case or medical management systems maintained for CDPH health plans; or those records used to make

EXHIBIT E
HIPAA Business Associate Addendum

decisions about individuals on behalf of CDPH. Color shall use the forms and processes developed by CDPH for this purpose and shall respond to requests for access to records transmitted by CDPH within fifteen (15) calendar days of receipt of the request by producing the records or verifying that there are none.

2. If Color maintains an Electronic Health Record with PHI, and an individual requests a copy of such information in an electronic format, Color shall provide such information in an electronic format to enable CDPH to fulfill its obligations under the HITECH Act, including but not limited to, 42 U.S.C. section 17935(e).
3. If Color receives data from CDPH that was provided to CDPH by the Social Security Administration, upon request by CDPH, Color shall provide CDPH with a list of all employees, contractors and agents who have access to the Social Security data, including employees, contractors and agents of its subcontractors and agents.

G. *Amendment of PHI.* To make any amendment(s) to PHI that CDPH directs or agrees to pursuant to 45 CFR section 164.526, in the time and manner designated by CDPH.

H. *Internal Practices.* To make Color's internal practices, books and records relating to the use and disclosure of PHI received from CDPH, or created or received by Color on behalf of CDPH, available to CDPH or to the Secretary in a time and manner designated by CDPH or by the Secretary, for purposes of determining CDPH's compliance with the HIPAA regulations. If any information needed for this purpose is in the exclusive possession of any other entity or person and the other entity or person fails or refuses to furnish the information to Color, Color shall so certify to CDPH and shall set forth the efforts it made to obtain the information.

I. *Documentation of Disclosures.* To document and make available to CDPH or (at the direction of CDPH) to an Individual such disclosures of PHI, and information related to such disclosures, necessary to respond to a proper request by the subject Individual for an accounting of disclosures of PHI, in accordance with the HITECH Act and its implementing regulations, including but not limited to 45 CFR part 164.528 and 42 U.S.C. section 17935(c). If Color maintains electronic health records for CDPH as of January 1, 2009, Color must provide an accounting of disclosures, including those disclosures for treatment, payment or health care operations, effective with disclosures on or after January 1, 2014. If Color acquires electronic health records for CDPH after January 1, 2009, Color must provide an accounting of disclosures, including those disclosures for treatment, payment or health care operations, effective with disclosures on or after the date the electronic health record is acquired, or on or after January 1, 2011, whichever date is later. The electronic accounting of disclosures shall be for disclosures during the three years prior to the request for an accounting.

J. *Breaches and Security Incidents.* During the term of the Agreement, Color agrees to implement reasonable systems for the discovery and prompt reporting of any breach or security incident, and to take the following steps:

1. ***Notice to CDPH.*** (1) To notify CDPH **as soon as practicable and without unreasonable delay, by telephone call plus email** upon the discovery of a Breach of unsecured PHI or PI in electronic media or in any other media if the PHI or PI was, or is reasonably believed to have been, accessed or acquired by an unauthorized person, or upon the discovery of a reasonably likely suspected Security Incident that involves data provided to CDPH by the Social Security Administration. (2) To notify CDPH **as soon as practicable and without unreasonable delay, by email** of the discovery of any reasonably likely suspected Security Incident. A breach shall be treated as discovered by Color as of the first day on which the breach is known, or by exercising reasonable diligence would have been

EXHIBIT E
HIPAA Business Associate Addendum

known, to any person (other than the person committing the breach) who is an employee, officer or other agent of Color.

Notice shall be provided to the CDPH Program Contract Manager, the CDPH Privacy Officer and the CDPH Information Security Officer. If the incident occurs after business hours or on a weekend or holiday and involves electronic PHI, notice shall be provided by calling the CDPH ITSD Service Desk. Notice shall be made using the "CDPH Privacy Incident Report" form, including all information known at the time. Color shall use the most current version of this form, which is posted on the CDPH Privacy Office website (www.CDPH.ca.gov).

Upon discovery of a breach or suspected security incident, intrusion or unauthorized access, use or disclosure of PHI or PI, Color shall take:

- a. Prompt corrective action to mitigate any risks or damages involved with the breach and to protect the operating environment; and
 - b. Any action pertaining to such unauthorized disclosure required by applicable Federal and State laws and regulations.
2. ***Investigation and Investigation Report.*** To immediately investigate such security incident, breach, or unauthorized access, use or disclosure of PHI or PI. Color shall cooperate in good faith with CDPH in the investigation of any Breach or Security Incident. CDPH preserves the right to participate in the investigation of a security incident involving its data or conduct its own independent investigation, and Color shall cooperate fully in such investigations. Within 72 hours of the discovery, Color shall submit an updated "CDPH Privacy Incident Report" containing the information marked with an asterisk and all other applicable information listed on the form, to the extent known at that time, to the CDPH Program Contract Manager, the CDPH Privacy Officer, and the CDPH Information Security Officer.
3. ***Complete Report.*** To provide a complete report of the investigation to the CDPH Program Contract Manager, the CDPH Privacy Officer, and the CDPH Information Security Officer within ten (10) working days of the discovery of the breach or unauthorized use or disclosure. The report shall be submitted on the "CDPH Privacy Incident Report" form and shall include an assessment of all known factors relevant to a determination of whether a breach occurred under applicable provisions of HIPAA, the HITECH Act, the HIPAA regulations and/or state law. The report shall also include a full, detailed corrective action plan, including information on measures that were taken to halt and/or contain the improper use or disclosure. If CDPH requests information in addition to that listed on the "CDPH Privacy Incident Report" form, Color shall make reasonable efforts to provide CDPH with such information. If necessary, a Supplemental Report may be used to submit revised or additional information after the completed report is submitted, by submitting the revised or additional information on an updated "CDPH Privacy Incident Report" form. CDPH will review and approve the determination of whether a breach occurred and individual notifications are required, and the corrective action plan.
4. ***Notification of Individuals.*** If the cause of a breach of PHI or PI is attributable to Color or its subcontractors, agents or vendors, Color shall notify individuals of the breach or unauthorized use or disclosure when notification is required under state or federal law and shall pay any costs of such notifications, as well as any costs associated with the breach. The notifications shall comply with the requirements set forth in California Civil Code section 1798.29 and 42 U.S.C. section 17932 and its implementing regulations, including, but not limited to, the requirement that the notifications be made without unreasonable delay and in no event later than 60 calendar days. The CDPH Program Contract Manager, the CDPH Privacy Officer, and the CDPH Information Security Officer shall approve the time, manner and content of any such notifications and their review and approval must be obtained before the notifications are made.

EXHIBIT E
HIPAA Business Associate Addendum

5. **Responsibility for Reporting of Breaches.** If the cause of a breach of PHI or PI is attributable to Color or its agents, subcontractors or vendors, Color, is responsible for all required reporting of the breach as specified in 42 U.S.C. section 17932 and its implementing regulations, including notification to media outlets and to the Secretary. If a breach of unsecured PHI involves more than 500 residents of the State of California or its jurisdiction, Color shall notify the Secretary of the breach immediately upon discovery of the breach. If Color has reason to believe that duplicate reporting of the same breach or incident may occur because its subcontractors, agents or vendors may report the breach or incident to CDPH in addition to Color, Color shall notify CDPH, and CDPH and Color may take appropriate action to prevent duplicate reporting. The breach reporting requirements of this paragraph are in addition to the reporting requirements set forth in subsection 1, above.
6. **CDPH Contact Information.** To direct communications to the above referenced CDPH staff, the Color shall initiate contact as indicated herein. CDPH reserves the right to make changes to the contact information below by giving written notice to the Color. Said changes shall not require an amendment to this Addendum or the Agreement to which it is incorporated.

CDPH Program Contract Manager	CDPH Privacy Officer	CDPH Information Security Officer
See the Scope of Work exhibit for Program Contract Manager information	Privacy Officer Privacy Office, c/o Office of Legal Services California Department of Public Health 1415 L Street, 5 th Floor Sacramento, CA 95814 Email: privacy@cdph.ca.gov Telephone: (877) 421-9634	Chief Information Security Officer Information Security Office California Department of Public Health P.O. Box 997413, MS 6302 Sacramento, CA 95899-7413 Email: cdphiso@cdph.ca.gov Telephone: IT Service Desk (916) 440-7000 or (800) 579-0874

- K. **Due Diligence.** Color shall exercise due diligence and shall take reasonable steps to ensure that it remains in compliance with this Addendum and is in compliance with applicable provisions of HIPAA, the HITECH Act and the HIPAA regulations, and that its agents, subcontractors and vendors are in compliance with their obligations as required by this Addendum.
- L. **Sanctions and/or Penalties.** Color understands that a failure to comply with the provisions of HIPAA, the HITECH Act and the HIPAA regulations that are applicable to Color may result in the imposition of sanctions and/or penalties on Color under HIPAA, the HITECH Act and the HIPAA regulations.

IV. Obligations of CDPH

CDPH agrees to:

- A. **Notice of Privacy Practices.** Provide Color with the Notice of Privacy Practices that CDPH produces in accordance with 45 CFR section 164.520, as well as any changes to such notice.

EXHIBIT E
HIPAA Business Associate Addendum

- B. *Permission by Individuals for Use and Disclosure of PHI.*** Provide Color with any changes in, or revocation of, permission by an Individual to use or disclose PHI, if such changes affect Color's permitted or required uses and disclosures.
- C. *Notification of Restrictions.*** Notify Color of any restriction to the use or disclosure of PHI that CDPH has agreed to in accordance with 45 CFR section 164.522, to the extent that such restriction may affect Color's use or disclosure of PHI.
- D. *Requests Conflicting with HIPAA Rules.*** Not request Color use or disclose PHI in any manner that would not be permissible under the HIPAA regulations if done by CDPH.

V. Audits, Inspection and Enforcement

- A.** From time to time, CDPH may inspect the facilities, systems, books and records of Business Associate to the extent they contain PHI subject to this Agreement to monitor compliance with the Agreement and this Addendum. Business Associate shall promptly remedy any violation of any provision of this Addendum and shall certify the same to the CDPH Privacy Officer in writing. The fact that CDPH inspects, or fails to inspect, or has the right to inspect, Business Associate's facilities, systems and procedures does not relieve Business Associate of its responsibility to comply with this Addendum, nor does CDPH's:
 - 1. Failure to detect; or
 - 2. Detection, but failure to notify Business Associate or require Business Associate's remediation of any unsatisfactory practices constitute acceptance of such practice or a waiver of CDPH's enforcement rights under the Agreement and this Addendum.
- B.** If Color is the subject of an audit, compliance review, or complaint investigation by the Secretary or the Office of Civil Rights, U.S. Department of Health and Human Services, that is related to the performance of its obligations pursuant to this HIPAA Color Addendum, Color shall notify CDPH and provide CDPH with a copy of any PHI or PI that Color provides to the Secretary or the Office of Civil Rights concurrently with providing such PHI or PI to the Secretary. Color is responsible for any civil penalties assessed due to an audit or investigation of Color, in accordance with 42 U.S.C. section 17934(c).

VI. *Requests for CDPH PHI or PI by Third Parties.* Color and its employees, agents, or subcontractors shall promptly transmit to the CDPH Program Contract Manager all requests seeking to compel disclosure of any CDPH PHI or PI requested by third parties to the agreement between Color and CDPH (except from an Individual for an accounting of disclosures of the individual's personal information pursuant to applicable state or federal law), including but not limited to, requests under the California Public Records Act, subpoenas, or court orders, unless prohibited from doing so by applicable state or federal law.

VII. Termination

- A. *Term.*** The Term of this Addendum shall commence as of the effective date of this Addendum and shall extend beyond the termination of the Agreement and shall terminate when all the PHI provided by CDPH to Color, or created or received by Color on behalf of CDPH, is destroyed or returned to CDPH, in accordance with 45 CFR part 164.504(e)(2)(ii)(J).
- B. *Termination for Cause by CDPH.*** In accordance with 45 CFR part 164.504(e)(1)(ii), upon CDPH's knowledge of a material breach or violation of this Addendum by Color, CDPH shall:
 - 1. Provide an opportunity for Color to cure the breach or end the violation and terminate the Agreement if Color does not cure the breach or end the violation within the time specified by CDPH; or

EXHIBIT E
HIPAA Business Associate Addendum

2. Immediately terminate the Agreement if Color has breached a material term of this Addendum and cure is not possible.

C. *Termination for Cause by Color.* . In accordance with 42 U.S.C. section 17934(b) of the HITECH Act and to the extent required by the HIPAA regulations, if Color knows of a material breach or violation by CDPH of this Addendum, it shall take the following steps:

1. Provide an opportunity for CDPH to cure the breach or end the violation and terminate the Agreement if CDPH does not cure the breach or end the violation within the time specified by Color; or
2. Immediately terminate the Agreement if CDPH has breached a material term of the Addendum and cure is not possible.

D. *Judicial or Administrative Proceedings.* Color will notify CDPH if it is named as a defendant in a criminal proceeding for a violation of HIPAA. CDPH may terminate the Agreement if Color is found guilty of a criminal violation of HIPAA. CDPH may terminate the Agreement if a finding or stipulation that Color has violated any standard or requirement of HIPAA, or other security or privacy laws is made in any administrative or civil proceeding in which Color is a party or has been joined.

E. *Effect of Termination.* Upon termination or expiration of the Agreement for any reason, Color shall return or destroy all PHI received from CDPH (or created or received by Business Associate on behalf of CDPH) that Color still maintains in any form, and shall retain no copies of such PHI. If return or destruction is not feasible, Color shall notify CDPH of the conditions that make the return or destruction infeasible, and the terms of this Business Associate Addendum shall continue to apply to such PHI. Color shall continue to extend the protections of this Addendum to such PHI, and shall limit further use of such PHI to those purposes that make the return or destruction of such PHI infeasible. This provision shall apply to PHI that is in the possession of subcontractors or agents of Color. Notwithstanding the foregoing, Color may retain copies of any PI or PHI to the extent Color is required to do so under Applicable Law or licensure requirements or as a CLIA-certified, College of American Pathologists-accredited laboratory and Covered Entity.

VIII. Miscellaneous Provisions

A. *Disclaimer.* CDPH makes no warranty or representation that compliance by Color with this Addendum, HIPAA or the HIPAA regulations will be adequate or satisfactory for Color's own purposes or that any information in Color's possession or control, or transmitted or received by Color, is or will be secure from unauthorized use or disclosure. Color is solely responsible for all decisions made by Color regarding the safeguarding of PHI.

B. *Amendment.* The parties acknowledge that federal and state laws relating to electronic data security and privacy are rapidly evolving and that amendment of this Addendum may be required to provide for procedures to ensure compliance with such developments. The parties specifically agree to take such action as is necessary to implement the standards and requirements of HIPAA, the HITECH Act, the HIPAA regulations and other applicable laws relating to the security or privacy of PHI. Upon CDPH's request, Color agrees to promptly enter into negotiations with CDPH concerning an amendment to this Addendum embodying written assurances consistent with the standards and requirements of HIPAA, the HITECH Act, the HIPAA regulations or other applicable laws. CDPH may terminate the Agreement upon thirty (30) days written notice in the event:

1. Color does not promptly enter into negotiations to amend this Addendum when requested by CDPH pursuant to this Section; or

EXHIBIT E
HIPAA Business Associate Addendum

2. Color does not enter into an amendment providing assurances regarding the safeguarding of PHI that CDPH in its sole discretion, deems sufficient to satisfy the standards and requirements of HIPAA and the HIPAA regulations.
- C. *Assistance in Litigation or Administrative Proceedings.*** Color shall make itself and any subcontractors, employees or agents assisting Color in the performance of its obligations under the Agreement, reasonably available to CDPH at no cost to CDPH to testify as witnesses (but not as expert witnesses) in the event of litigation or administrative proceedings being commenced against CDPH, its directors, officers or employees based upon claimed violation of HIPAA, the HIPAA regulations or other laws relating to security and privacy, which involves inactions or actions by Color, except where Color or its subcontractor, employee or agent is a named adverse party.
- D. *No Third-Party Beneficiaries.*** Nothing express or implied in the terms and conditions of this Addendum is intended to confer, nor shall anything herein confer, upon any person other than CDPH or Color and their respective successors or assignees, any rights, remedies, obligations or liabilities whatsoever.
- E. *Interpretation.*** The terms and conditions in this Addendum shall be interpreted as broadly as necessary to implement and comply with HIPAA, the HITECH Act, the HIPAA regulations and applicable state laws. The parties agree that any ambiguity in the terms and conditions of this Addendum shall be resolved in favor of a meaning that complies and is consistent with HIPAA, the HITECH Act and the HIPAA regulations.
- F. *Regulatory References.*** A reference in the terms and conditions of this Addendum to a section in the HIPAA regulations means the section as in effect or as amended.
- G. *Survival.*** The respective rights and obligations of Color under Section VII.E of this Addendum shall survive the termination or expiration of the Agreement.
- H. *No Waiver of Obligations.*** No change, waiver or discharge of any liability or obligation hereunder on any one or more occasions shall be deemed a waiver of performance of any continuing or other obligation, or shall prohibit enforcement of any obligation, on any other occasion.

EXHIBIT E
HIPAA Business Associate Addendum

I. Personnel Controls

- A. *Employee Training.*** All of the Color's workforce members (workforce member) who assist in the performance of functions or activities on behalf of CDPH, or access or disclose CDPH PHI or PI must complete information privacy and security training, at least annually, at Color's expense. Each workforce member who receives information privacy and security training must sign a certification, indicating the workforce member's name and the date on which the training was completed. These certifications must be retained for a period of six (6) years following contract termination. Color shall provide CDPH with its employee's certifications within five (5) business days of a request by CDPH for the employee's certifications.
- B. *Employee Discipline.*** Appropriate sanctions must be applied against workforce members who fail to comply with privacy policies and procedures or any provisions of these requirements, including termination of employment where appropriate.
- C. *Confidentiality Statement.*** All persons that will be working with CDPH PHI or PI must sign a confidentiality statement that includes, at a minimum, General Use, Security and Privacy Safeguards, Unacceptable Use, and Enforcement Policies. The statement must be signed by the workforce member prior to access to CDPH PHI or PI. The statement must be renewed annually. Color shall retain each workforce member's written confidentiality statement for CDPH inspection for a period of six (6) years following contract termination.
- D. *Workforce Member Assessment.*** Before a member of the Contractor's workforce may access CDPH PHI or PI, Contractor must ensure that all workforce members that will have access to CDPH PCI have been informally assessed to assure that there is no indication that the workforce member may present a risk to the security or integrity of CDPH PHI or PI. Contractor shall retain each workforce member's assessment documentation, whether in physical or electronic format, for a period of three (3) years following contract termination.

II. Technical Security Controls

- A. *Workstation/Laptop encryption.*** All workstations and laptops that process and/or store CDPH PHI or PI must be encrypted using a FIPS 140-2 certified algorithm which is 128bit or higher, such as Advanced Encryption Standard (AES). The encryption solution must be full disk unless approved by the CDPH Information Security Office.
- B. *Server Security.*** Servers containing unencrypted CDPH PHI or PI must have sufficient administrative, physical, and technical controls in place to protect that data, based upon a risk assessment/system security review.
- C. *Minimum Necessary.*** Only the minimum necessary amount of CDPH PHI or PI required to perform necessary business functions may be copied, downloaded, or exported.
- D. *Removable media devices.*** All electronic files that contain CDPH PHI or PI data must be encrypted when stored on any removable media or portable device (i.e. USB thumb drives, floppies, CD/DVD, Blackberry, backup tapes etc.). Encryption must be a FIPS 140-2 certified algorithm which is 128bit or higher, such as AES.

EXHIBIT E
HIPAA Business Associate Addendum

- E. *Antivirus software.*** All workstations, laptops and other systems that process and/or store CDPH PHI or PI must install and actively use comprehensive anti-virus software solution with automatic updates scheduled at least daily.
- F. *Patch Management.*** All workstations, laptops and other systems that process and/or store CDPH PHI or PI must have critical security patches applied, with system reboot if necessary. There must be a documented patch management process which determines installation timeframe based on risk assessment and vendor recommendations. At a maximum, all applicable patches must be installed within thirty (30) days of vendor release.
- G. *User IDs and Password Controls.*** All users must be issued a unique user name for accessing CDPH PHI or PI. Username must be promptly disabled, deleted, or the password changed upon the transfer or termination of an employee with knowledge of the password, at maximum within 24 hours. Passwords are not to be shared. Passwords must be at least eight characters and must be a non-dictionary word. Passwords must not be stored in readable format on the computer. Passwords must be changed every ninety (90) days, preferably every sixty (60) days. Passwords must be changed if revealed or compromised. Passwords must be composed of characters from at least three of the following four groups from the standard keyboard:
- Upper case letters (A-Z)
 - Lower case letters (a-z)
 - Arabic numerals (0-9)
 - Non-alphanumeric characters (punctuation symbols)
- H. *Data Destruction.*** When no longer needed, all CDPH PHI or PI must be wiped using the Gutmann or US Department of Defense (DoD) 5220.22-M (7 Pass) standard, or by degaussing. Media may also be physically destroyed in accordance with NIST Special Publication 800-88. Other methods require prior written permission of the CDPH Information Security Office.
- I. *System Timeout.*** The system providing access to CDPH PHI or PI must provide an automatic timeout, requiring re-authentication of the user session after no more than 20 minutes of inactivity.
- J. *Warning Banners.*** All systems providing access to CDPH PHI or PI must display a warning banner stating that data is confidential, systems are logged, and system use is for business purposes only by authorized users. User must be directed to log off the system if they do not agree with these requirements.
- K. *System Logging.*** The system must maintain an automated audit trail which can identify the user or system process which initiates a request for CDPH PHI or PI, or which alters CDPH PHI or PI. The audit trail must be date and time stamped, must log both successful and failed accesses, must be read only, and must be restricted to authorized users. If CDPH PHI or PI is stored in a database, database logging functionality must be enabled. Audit trail data must be archived for at least three (3) years after occurrence.
- L. *Access Controls.*** The system providing access to CDPH PHI or PI must use role based access controls for all user authentications, enforcing the principle of least privilege.

EXHIBIT E
HIPAA Business Associate Addendum

- M. *Transmission encryption.*** All data transmissions of CDPH PHI or PI outside the secure internal network must be encrypted using a FIPS 140-2 certified algorithm which is 128bit or higher, such as AES. Encryption can be end to end at the network level, or the data files containing PHI can be encrypted. This requirement pertains to any type of PHI or PI in motion such as website access, file transfer, and E-Mail.
- N. *Intrusion Detection.*** All systems involved in accessing, holding, transporting, and protecting CDPH PHI or PI that are accessible via the Internet must be protected by a comprehensive intrusion detection and prevention solution.

III. Audit Controls

- A. *System Security Review.*** All systems processing and/or storing CDPH PHI or PI must have at least an annual system risk assessment/security review which provides assurance that administrative, physical, and technical controls are functioning effectively and providing adequate levels of protection. Reviews should include vulnerability scanning tools.
- B. *Log Reviews.*** All systems processing and/or storing CDPH PHI or PI must have a routine procedure in place to review system logs for unauthorized access.
- C. *Change Control.*** All systems processing and/or storing CDPH PHI or PI must have a documented change control procedure that ensures separation of duties and protects the confidentiality, integrity and availability of data.

IV. Business Continuity / Disaster Recovery Controls

- A. *Emergency Mode Operation Plan.*** Color must establish a documented plan to enable continuation of critical business processes and protection of the security of electronic CDPH PHI or PI in the event of an emergency. Emergency means any circumstance or situation that causes normal computer operations to become unavailable for use in performing the work required under the Agreement for more than 24 hours.
- B. *Data Backup Plan.*** Color must have established documented procedures to backup CDPH PHI to maintain retrievable exact copies of CDPH PHI or PI. The plan must include a regular schedule for making backups, storing backups offsite, an inventory of backup media, and an estimate of the amount of time needed to restore CDPH PHI or PI should it be lost. At a minimum, the schedule must be a weekly full backup and monthly offsite storage of CDPH data.

V. Paper Document Controls

- A. *Supervision of Data.*** CDPH PHI or PI in paper form shall not be left unattended at any time, unless it is locked in a file cabinet, file room, desk or office. Unattended means that information is not being observed by a workforce member authorized to access the information. CDPH PHI or PI in paper form shall not be left unattended at any time in vehicles or planes and shall not be checked in baggage on commercial airplanes.
- B. *Escorting Visitors.*** Visitors to areas where CDPH PHI or PI is contained shall be escorted and CDPH PHI or PI shall be kept out of sight while visitors are in the area.
- C. *Confidential Destruction.*** CDPH PHI or PI must be disposed of through confidential means, such as cross cut shredding and pulverizing.

EXHIBIT E
HIPAA Business Associate Addendum

- D. *Removal of Data.*** CDPH PHI or PI must not be removed from the premises of the Color except with express written permission of CDPH.
- E. *Faxing.*** Faxes containing CDPH PHI or PI shall not be left unattended and fax machines shall be in secure areas. Faxes shall contain a confidentiality statement notifying persons receiving faxes in error to destroy them. Fax numbers shall be verified with the intended recipient before sending the fax.
- F. *Mailing.*** Mailings of CDPH PHI or PI shall be sealed and secured from damage or inappropriate viewing of PHI or PI to the extent possible. Mailings which include 500 or more individually identifiable records of CDPH PHI or PI in a single package shall be sent using a tracked mailing method which includes verification of delivery and receipt, unless the prior written permission of CDPH to use another method is obtained.

Attachment _____
HIPAA Business Associate Addendum |

- A. *Notice of Privacy Practices.*** Provide Business Associate with the Notice of Privacy Practices that CDPH produces in accordance with 45 CFR section 164.520, as well as any changes to such notice.
- B. *Permission by Individuals for Use and Disclosure of PHI.*** Provide Business Associate with any changes in, or revocation of, permission by an Individual to use or disclose PHI, if such changes affect Business Associate's permitted or required uses and disclosures.
- C. *Notification of Restrictions.*** Notify Business Associate of any restriction to the use or disclosure of PHI that CDPH has agreed to in accordance with 45 CFR section 164.522, to the extent that such restriction may affect Business Associate's use or disclosure of PHI.
- D. *Requests Conflicting with HIPAA Rules.*** Not request Business Associate use or disclose PHI in any manner that would not be permissible under the HIPAA regulations if done by CDPH.

V. Audits, Inspection and Enforcement

- A.** From time to time, CDPH may inspect the facilities, systems, books and records of Business Associate to monitor compliance with the Agreement and this Addendum. Business Associate shall promptly remedy any violation of any provision of this Addendum and shall certify the same to the CDPH Privacy Officer in writing. The fact that CDPH inspects, or fails to inspect, or has the right to inspect, Business Associate's facilities, systems and procedures does not relieve Business Associate of its responsibility to comply with this Addendum, nor does CDPH's:
 - 1. Failure to detect; or
 - 2. Detection, but failure to notify Business Associate or require Business Associate's remediation of any unsatisfactory practices constitute acceptance of such practice or a waiver of CDPH's enforcement rights under the Agreement and this Addendum.
- B.** If Business Associate is the subject of an audit, compliance review, or complaint investigation by the Secretary or the Office of Civil Rights, U.S. Department of Health and Human Services, that is related to the performance of its obligations pursuant to this HIPAA Business Associate Addendum, Business Associate shall notify CDPH and provide CDPH with a copy of any PHI or PI that Business Associate provides to the Secretary or the Office of Civil Rights concurrently with providing such PHI or PI to the Secretary. Business Associate is responsible for any civil penalties assessed due to an audit or investigation of Business Associate, in accordance with 42 U.S.C. section 17934(c).

VI. *Requests for CDPH PHI or PI by Third Parties.* Business Associate and its employees, agents, or subcontractors shall promptly transmit to the CDPH Program Contract Manager all requests for disclosure of any CDPH PHI or PI requested by third parties to the agreement between Business Associate and CDPH (except from an Individual for an accounting of disclosures of the individual's personal information pursuant to applicable state or federal law), including but not limited to, requests under the California Public Records Act, subpoenas, or court orders, unless prohibited from doing so by applicable state or federal law.

VII. Termination

- A. *Term.*** The Term of this Addendum shall commence as of the effective date of this Addendum and shall extend beyond the termination of the Agreement and shall terminate when all the PHI provided by CDPH to Business Associate, or created or received by Business Associate on behalf of CDPH, is destroyed or returned to CDPH, in accordance with 45 CFR part 164.504(e)(2)(ii)(J).

Attachment _____
 HIPAA Business Associate Addendum

- B. Termination for Cause by CDPH.** In accordance with 45 CFR part 164.504(e)(1)(ii), upon CDPH's knowledge of a material breach or violation of this Addendum by Business Associate, CDPH shall:
1. Provide an opportunity for Business Associate to cure the breach or end the violation and terminate the Agreement if Business Associate does not cure the breach or end the violation within the time specified by CDPH; or
 2. Immediately terminate the Agreement if Business Associate has breached a material term of this Addendum and cure is not possible.
- C. Termination for Cause by Business Associate.** . In accordance with 42 U.S.C. section 17934(b) of the HITECH Act and to the extent required by the HIPAA regulations, if Business Associate knows of a material breach or violation by CDPH of this Addendum, it shall take the following steps:
1. Provide an opportunity for CDPH to cure the breach or end the violation and terminate the Agreement if CDPH does not cure the breach or end the violation within the time specified by Business Associate; or
 2. Immediately terminate the Agreement if CDPH has breached a material term of the Addendum and cure is not possible.
- D. Judicial or Administrative Proceedings.** Business Associate will notify CDPH if it is named as a defendant in a criminal proceeding for a violation of HIPAA. CDPH may terminate the Agreement if Business Associate is found guilty of a criminal violation of HIPAA. CDPH may terminate the Agreement if a finding or stipulation that Business Associate has violated any standard or requirement of HIPAA, or other security or privacy laws is made in any administrative or civil proceeding in which Business Associate is a party or has been joined.
- E. Effect of Termination.** Upon termination or expiration of the Agreement for any reason, Business Associate shall return or destroy all PHI received from CDPH (or created or received by Business Associate on behalf of CDPH) that Business Associate still maintains in any form, and shall retain no copies of such PHI. If return or destruction is not feasible, Business Associate shall notify CDPH of the conditions that make the return or destruction infeasible, and CDPH and Business Associate shall determine the terms and conditions under which Business Associate may retain the PHI. Business Associate shall continue to extend the protections of this Addendum to such PHI, and shall limit further use of such PHI to those purposes that make the return or destruction of such PHI infeasible. This provision shall apply to PHI that is in the possession of subcontractors or agents of Business Associate.

VIII. Miscellaneous Provisions

- A. Disclaimer.** CDPH makes no warranty or representation that compliance by Business Associate with this Addendum, HIPAA or the HIPAA regulations will be adequate or satisfactory for Business Associate's own purposes or that any information in Business Associate's possession or control, or transmitted or received by Business Associate, is or will be secure from unauthorized use or disclosure. Business Associate is solely responsible for all decisions made by Business Associate regarding the safeguarding of PHI.
- B. Amendment.** The parties acknowledge that federal and state laws relating to electronic data security and privacy are rapidly evolving and that amendment of this Addendum may be required to provide for procedures to ensure compliance with such developments. The parties specifically agree to take such action as is necessary to implement the standards and requirements of HIPAA, the HITECH Act, the HIPAA regulations and other applicable laws relating to the security or privacy of PHI. Upon CDPH's request, Business Associate agrees to promptly enter into negotiations with CDPH concerning an

Attachment _____
HIPAA Business Associate Addendum |

amendment to this Addendum embodying written assurances consistent with the standards and requirements of HIPAA, the HITECH Act, the HIPAA regulations or other applicable laws. CDPH may terminate the Agreement upon thirty (30) days written notice in the event:

1. Business Associate does not promptly enter into negotiations to amend this Addendum when requested by CDPH pursuant to this Section; or
2. Business Associate does not enter into an amendment providing assurances regarding the safeguarding of PHI that CDPH in its sole discretion, deems sufficient to satisfy the standards and requirements of HIPAA and the HIPAA regulations.

C. Assistance in Litigation or Administrative Proceedings. Business Associate shall make itself and any subcontractors, employees or agents assisting Business Associate in the performance of its obligations under the Agreement, available to CDPH at no cost to CDPH to testify as witnesses, or otherwise, in the event of litigation or administrative proceedings being commenced against CDPH, its directors, officers or employees based upon claimed violation of HIPAA, the HIPAA regulations or other laws relating to security and privacy, which involves inactions or actions by Business Associate, except where Business Associate or its subcontractor, employee or agent is a named adverse party.

D. No Third-Party Beneficiaries. Nothing express or implied in the terms and conditions of this Addendum is intended to confer, nor shall anything herein confer, upon any person other than CDPH or Business Associate and their respective successors or assignees, any rights, remedies, obligations or liabilities whatsoever.

E. Interpretation. The terms and conditions in this Addendum shall be interpreted as broadly as necessary to implement and comply with HIPAA, the HITECH Act, the HIPAA regulations and applicable state laws. The parties agree that any ambiguity in the terms and conditions of this Addendum shall be resolved in favor of a meaning that complies and is consistent with HIPAA, the HITECH Act and the HIPAA regulations.

F. Regulatory References. A reference in the terms and conditions of this Addendum to a section in the HIPAA regulations means the section as in effect or as amended.

G. Survival. The respective rights and obligations of Business Associate under Section VII.E of this Addendum shall survive the termination or expiration of the Agreement.

H. No Waiver of Obligations. No change, waiver or discharge of any liability or obligation hereunder on any one or more occasions shall be deemed a waiver of performance of any continuing or other obligation, or shall prohibit enforcement of any obligation, on any other occasion.

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HIPAA Business Associate Addendum

I. Personnel Controls

- A. *Employee Training.*** All of the Business Associate's workforce members (workforce member) who assist in the performance of functions or activities on behalf of CDPH, or access or disclose CDPH PHI or PI must complete information privacy and security training, at least annually, at Business Associate's expense. Each workforce member who receives information privacy and security training must sign a certification, indicating the workforce member's name and the date on which the training was completed. These certifications must be retained for a period of six (6) years following contract termination. Business Associate shall provide CDPH with its employee's certifications within five (5) business days of a request by CDPH for the employee's certifications.
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II. Technical Security Controls

- A. *Workstation/Laptop encryption.*** All workstations and laptops that process and/or store CDPH PHI or PI must be encrypted using a FIPS 140-2 certified algorithm which is 128bit or higher, such as Advanced Encryption Standard (AES). The encryption solution must be full disk unless approved by the CDPH Information Security Office.
- B. *Server Security.*** Servers containing unencrypted CDPH PHI or PI must have sufficient administrative, physical, and technical controls in place to protect that data, based upon a risk assessment/system security review.
- C. *Minimum Necessary.*** Only the minimum necessary amount of CDPH PHI or PI required to perform necessary business functions may be copied, downloaded, or exported.
- D. *Removable media devices.*** All electronic files that contain CDPH PHI or PI data must be encrypted when stored on any removable media or portable device (i.e. USB thumb drives, floppies, CD/DVD, Blackberry, backup tapes etc.). Encryption must be a FIPS 140-2 certified algorithm which is 128bit or higher, such as AES.

Attachment __
HIPAA Business Associate Addendum

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- H. *Data Destruction.*** When no longer needed, all CDPH PHI or PI must be wiped using the Gutmann or US Department of Defense (DoD) 5220.22-M (7 Pass) standard, or by degaussing. Media may also be physically destroyed in accordance with NIST Special Publication 800-88. Other methods require prior written permission of the CDPH Information Security Office.
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Attachment ___
HIPAA Business Associate Addendum

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- C. *Change Control.*** All systems processing and/or storing CDPH PHI or PI must have a documented change control procedure that ensures separation of duties and protects the confidentiality, integrity and availability of data.

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- A. *Emergency Mode Operation Plan.*** Business Associate must establish a documented plan to enable continuation of critical business processes and protection of the security of electronic CDPH PHI or PI in the event of an emergency. Emergency means any circumstance or situation that causes normal computer operations to become unavailable for use in performing the work required under the Agreement for more than 24 hours.
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V. Paper Document Controls

- A. *Supervision of Data.*** CDPH PHI or PI in paper form shall not be left unattended at any time, unless it is locked in a file cabinet, file room, desk or office. Unattended means that information is not being observed by a workforce member authorized to access the information. CDPH PHI or PI in paper form shall not be left unattended at any time in vehicles or planes and shall not be checked in baggage on commercial airplanes.
- B. *Escorting Visitors.*** Visitors to areas where CDPH PHI or PI is contained shall be escorted and CDPH PHI or PI shall be kept out of sight while visitors are in the area.
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Attachment ___
HIPAA Business Associate Addendum |

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FEMA PROVISIONS

1. EQUAL EMPLOYMENT OPPORTUNITY

During the performance of this contract, the contractor agrees as follows:

- A. The contractor will not discriminate against any employee or applicant for employment because of race, color, religion, sex, sexual orientation, gender identity, or national origin. The contractor will take affirmative action to ensure that applicants are employed, and that employees are treated during employment without regard to their race, color, religion, sex, sexual orientation, gender identity, or national origin. Such action shall include, but not be limited to the following:

Employment, upgrading, demotion, or transfer; recruitment or recruitment advertising; layoff or termination; rates of pay or other forms of compensation; and selection for training, including apprenticeship. The contractor agrees to post in conspicuous places, available to employees and applicants for employment, notices to be provided setting forth the provisions of this nondiscrimination clause.

- B. The contractor will, in all solicitations or advertisements for employees placed by or on behalf of the contractor, state that all qualified applicants will receive consideration for employment without regard to race, color, religion, sex, sexual orientation, gender identity, or national origin.
- C. The contractor will not discharge or in any other manner discriminate against any employee or applicant for employment because such employee or applicant has inquired about, discussed, or disclosed the compensation of the employee or applicant or another employee or applicant. This provision shall not apply to instances in which an employee who has access to the compensation information of other employees or applicants as a part of such employee's essential job functions discloses the compensation of such other employees or applicants to individuals who do not otherwise have access to such information, unless such disclosure is in response to a formal complaint or charge, in furtherance of an investigation, proceeding, hearing, or action, including an investigation conducted by the employer, or is consistent with the contractor's legal duty to furnish information.
- D. The contractor will send to each labor union or representative of workers with which he has a collective bargaining agreement or other contract or understanding, a notice to be provided advising the said labor union or workers' representatives of the contractor's commitments under this section, and shall post copies of the notice in conspicuous places available to employees and applicants for employment.
- E. The contractor will comply with all provisions of Executive Order 11246 of September 24, 1965, and of the rules, regulations, and relevant orders of the Secretary of Labor.
- F. The contractor will furnish all information and reports required by Executive Order 11246 of September 24, 1965, and by rules, regulations, and orders of the Secretary of Labor, or pursuant thereto, and will permit access to his books, records, and accounts by the administering agency and the Secretary of Labor for purposes of investigation to ascertain compliance with such rules, regulations, and orders.
- G. In the event of the contractor's noncompliance with the nondiscrimination clauses of this contract or with any of the said rules, regulations, or orders, this contract may be canceled, terminated, or suspended in whole or in part and the contractor may be declared ineligible for further Government contracts or federally assisted construction contracts in accordance with procedures authorized in Executive Order 11246 of September 24, 1965, and such other sanctions may be imposed and remedies invoked as provided in Executive Order 11246 of September 24, 1965, or by rule, regulation, or order of the Secretary of Labor, or as otherwise provided by law.
- H. The contractor will include the portion of the sentence immediately preceding paragraph (1) and the provisions of paragraphs (1) through (8) in every subcontract or purchase order unless exempted by rules,

regulations, or orders of the Secretary of Labor issued pursuant to section 204 of Executive Order 11246 of September 24, 1965, so that such provisions will be binding upon each subcontractor or vendor. The contractor will take such action with respect to any subcontract or purchase order as the administering agency may direct as a means of enforcing such provisions, including sanctions for noncompliance:

Provided, however, that in the event a contractor becomes involved in, or is threatened with, litigation with a subcontractor or vendor as a result of such direction by the administering agency, the contractor may request the United States to enter into such litigation to protect the interests of the United States.

The applicant further agrees that it will be bound by the above equal opportunity clause with respect to its own employment practices when it participates in federally assisted construction work: Provided, That if the applicant so participating is a State or local government, the above equal opportunity clause is not applicable to any agency, instrumentality or subdivision of such government which does not participate in work on or under the contract.

The applicant agrees that it will assist and cooperate actively with the administering agency and the Secretary of Labor in obtaining the

compliance of contractors and subcontractors with the equal opportunity clause and the rules, regulations, and relevant orders of the Secretary of Labor, that it will furnish the administering agency and the Secretary of Labor such information as they may require for the supervision of such compliance, and that it will otherwise assist the administering agency in the discharge of the agency's primary responsibility for securing compliance.

The applicant further agrees that it will refrain from entering into any contract or contract modification subject to Executive Order 11246 of September 24, 1965, with a contractor debarred from, or who has not demonstrated eligibility for, Government contracts and federally assisted construction contracts pursuant to the Executive Order and will carry out such sanctions and penalties for violation of the equal opportunity clause as may be imposed upon

2. CONTRACT WORK HOURS AND SAFETY STANDARDS ACT

Compliance with the Contract Work Hours and Safety Standards Act.

- A. ***Overtime requirements.*** No contractor or subcontractor contracting for any part of the contract work which may require or involve the employment of laborers or mechanics shall require or permit any such laborer or mechanic in any workweek in which he or she is employed on such work to work in excess of forty hours in such workweek unless such laborer or mechanic receives compensation at a rate not less than one and one-half times the basic rate of pay for all hours worked in excess of forty hours in such workweek.
- B. ***Violation; liability for unpaid wages; liquidated damages.*** In the event of any violation of the clause set forth in paragraph (b)(1) of this section the contractor and any subcontractor responsible therefor shall be liable for the unpaid wages. In addition, such contractor and subcontractor shall be liable to the United States (in the case of work done under contract for the District of Columbia or a territory, to such District or to such territory), for liquidated damages. Such liquidated damages shall be computed with respect to each individual laborer or mechanic, including watchmen and guards, employed in violation of the clause set forth in paragraph (b)(1) of this section, in the sum of \$27 for each calendar day on which such individual was required or permitted to work in excess of the standard workweek of forty hours without payment of the overtime wages required by the clause set forth in paragraph (b)(1) of this section.
- C. ***Withholding for unpaid wages and liquidated damages.*** The State of California shall upon its own action or upon written request of an authorized representative of the Department of Labor withhold or cause to be withheld, from any moneys payable on account of work performed by the contractor or subcontractor under any such contract or any other Federal contract with the same prime contractor, or any other federally-assisted contract subject to the Contract Work Hours and Safety Standards Act, which is held by the same prime contractor, such sums as may be determined to be necessary to satisfy any liabilities of such contractor

or subcontractor for unpaid wages and liquidated damages as provided in the clause set forth in paragraph (b)(2) of this section.

- D. **Subcontracts.** The contractor or subcontractor shall insert in any subcontracts the clauses set forth in paragraph (b)(1) through (4) of this section and also a clause requiring the subcontractors to include these clauses in any lower tier subcontracts. The prime contractor shall be responsible for compliance by any subcontractor or lower tier subcontractor with the clauses set forth in paragraphs (b)(1) through (4) of this section.

3. CLEAN AIR ACT

- A. The contractor agrees to comply with all applicable standards, orders, or regulations issued pursuant to the Clean Air Act, as amended, 42 U.S.C. Section 7401 et seq.
- B. The contractor agrees to report each violation to the California Air Resources Board and understands and agrees that the California Air Resources Board will, in turn, report each violation as required to assure notification to the Department of Resources Recycling and Recovery, the California Governor's Office of Emergency Services, Federal Emergency Management Agency (FEMA), and the appropriate Environmental Protection Agency Regional Office.
- C. The contractor agrees to include these requirements in each subcontract exceeding \$150,000 financed in whole or in part with Federal assistance provided by FEMA.

4. THE FEDERAL WATER POLLUTION CONTROL ACT

- A. The contractor agrees to comply with all applicable standards, orders, or regulations issued pursuant to the Federal Water Pollution Control Act, as amended, 33 U.S.C. Sections 1251 et seq.
- B. The contractor agrees to report each violation to the State Water Resources Control Board and understands and agrees that the State Water Resources Control Board will, in turn, report each violation as required to assure notification to the Federal Emergency Management Agency (FEMA), and the appropriate Environmental Protection Agency Regional Office.
- C. The contractor agrees to include these requirements in each subcontract exceeding \$150,000 financed in whole or in part with Federal assistance provided by FEMA.

5. DEBARMENT AND SUSPENSION CLAUSE

- A. This contract is a covered transaction for purposes of 2 C.F.R. pt. 180 and 2 C.F.R. pt. 3000. As such the contractor is required to verify that none of the contractor, its principals (defined at 2 C.F.R. § 180.995), or its affiliates (defined at 2 C.F.R. § 180.905) are excluded (defined at 2 C.F.R. § 180.940) or disqualified (defined at 2 C.F.R. § 180.935).
- B. The contractor must comply with 2 C.F.R. pt. 180, subpart C and 2 C.F.R. pt. 3000, subpart C and must include a requirement to comply with these regulations in any lower tier covered transaction it enters into.
- C. This certification is a material representation of fact relied upon by the State of California. If it is later determined that the contractor did not comply with 2 C.F.R. pt. 180, subpart C and 2 C.F.R. pt. 3000, subpart C, in addition to remedies available to the State of California, the Federal Government may pursue available remedies, including but not limited to suspension and/or debarment.
- D. The bidder or proposer agrees to comply with the requirements of 2 C.F.R. pt. 180, subpart C and 2 C.F.R. pt. 3000, subpart C while this offer is valid and throughout the period of any contract that may arise from this offer. The bidder or proposer further agrees to include a provision requiring such compliance in its lower tier covered transactions.

6. BYRD ANTI-LOBBYING CLAUSE

Byrd Anti-Lobbying Amendment, 31 U.S.C. § 1352 (as amended). Contractors who apply or bid for an award of \$100,000 or more shall file the required certification. Each tier certifies to the tier above that it will not and has not used Federal appropriated funds to pay any person or organization for influencing or attempting to influence an officer or employee of any agency, a member of Congress, officer or employee of Congress, or an employee of a member of Congress in connection with obtaining any Federal contract, grant, or any other award covered by 31 U.S.C. § 1352. Each tier shall also disclose any lobbying with non-Federal funds that takes place in connection with obtaining any Federal award. Such disclosures are forwarded from tier to tier up to the recipient.

APPENDIX A, 44 C.F.R. PART 18- CERTIFICATION REGARDING LOBBYING

The undersigned [Contractor] certifies, to the best of his or her knowledge, that:

- A. No Federal appropriated funds have been paid or will be paid, by or on behalf of the undersigned, to any person for influencing or attempting to influence an officer or employee of an agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any Federal contract, the making of any Federal grant, the making of any Federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan, or cooperative agreement.
- B. If any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this Federal contract, grant, loan, or cooperative agreement, the undersigned shall complete and submit Standard Form- LLL, "Disclosure Form to Report Lobbying," in accordance with its instructions.
- C. The undersigned shall require that the language of this certification be included in the award documents for all subawards at all tiers (including subcontracts, subgrants, and contracts under grants, loans, and cooperative agreements) and that all subrecipients shall certify and disclose accordingly.

This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by 31, U.S.C. § 1352 (as amended by the Lobbying Disclosure Act of 1995). Any person who fails to file the required certification shall be subject to a civil penalty of not less than \$10,000 and not more than \$100,000 for each such failure.

The Contractor certifies or affirms the truthfulness and accuracy of each statement of its certification and disclosure, if any. In addition, the Contractor understands and agrees that the provisions of 31 U.S.C. § 3801 et seq., apply to this certification and disclosure, if any.

Signature of Contractor's Authorized Official

Name and Title of Contractor's Authorized Official

Date:

7. PROCUREMENT OF RECOVERED MATERIALS

- A. In the performance of this contract the Contractor shall make maximum use of products containing recovered materials that are EPA- designated items unless the product cannot be acquired-
 - i. Competitively within a timeframe providing for compliance with the contract performance schedule;
 - ii. Meeting contract performance requirements; or
 - iii. At a reasonable price.
- B. Information about this requirement is available at EPA's Comprehensive Procurement Guidelines web site, <http://www.epa.gov/cpg/>. The list of EPA-designate items is available at <https://www.epa.gov/smm/comprehensive-procurement-guideline-cpg-program>.
- C. The Contractor also agrees to comply with all other applicable requirements of Section 6002 of the Solid Waste Disposal Act.

8. ACCESS TO RECORDS

The following access to records requirements apply to this contract:

- A. The Contractor agrees to provide the State of California, the FEMA Administrator, the Controller General of the United States, or any of their authorized representatives access to any books, documents, papers, and records of the Contractor which are directly pertinent to this contract for the purposes of making audits, examinations, excerpts, and transcriptions.
- B. The Contractor agrees to permit any of the foregoing parties to reproduce by any means whatsoever of to copy excerpts and transcriptions as reasonably needed.
- C. The contractor agrees to provide the FEMA Administrator or his authorized representative access to construction or other work sites pertaining to the work being completed under the contract.
- D. In compliance with the Disaster Recovery Act of 2018, the State of California and the Contractor acknowledge and agree that no language in this contract is intended to prohibit audits or internal reviews by the FEMA Administrator or the Comptroller General of the United States.

9. DHS SEAL, LOGO, AND FLAGS

The contractor shall not use the DHS seal(s), logos, crests, or reproductions of flags or likenesses of DHS agency officials without specific FEMA pre-approval.

10. COMPLIANCE WITH FEDERAL LAW, REGULATIONS, AND EXECUTIVE ORDERS

This is an acknowledgement that FEMA financial assistance will be used to fund all or a portion of the contract only. The contractor will comply with all federal law, regulations, executive orders, FEMA policies, procedures, and directives.

11. NO OBLIGATION BY FEDERAL GOVERNMENT

The Federal Government is not a party to this contract and is not subject to any obligations or liabilities to the non-Federal entity, contractor, or any other party pertaining to any matter resulting from the contract.

12. PROGRAM FRAUD AND FALSE OR FRAUDULENT STATEMENTS OR RELATED ACTS

The contractor acknowledges the 31 U.S.C. Chapter 38 (Administrative Remedies for False Claims and Statements) applies to the contractor's action pertaining to this contract.