



**APPLICATION**  
**FOR**  
**HEMOGLOBIN VENDOR AGREEMENTS**

**July 1, 2011 – June 30, 2012**

**Due Date: October 14, 2011**

California Department of Public Health  
Genetic Disease Screening Program  
850 Marina Bay Parkway, F175  
Richmond, CA 94804

**This application package contains the following:**

A. Application Attachments

<b>Attachment #</b>	<b>Attachment Name</b>
Attachment 1	Vendor Information
Attachment 2	Payee Data Record
Attachment 3	Contractor Certification Clause
Attachment 4	Darfur Contracting Act

B. Sample Exhibits

<b>Exhibit #</b>	<b>Exhibit Name</b>
Exhibit A1	Standard Agreement
Exhibit A	Scope of Work
Exhibit A- Attachment I	Quarterly Summary Report
Exhibit B	Budget Detail and Payment Provisions
Exhibit B – Attachment I	Vendor Payment Provisions
Exhibit B- Attachment II	Sample Invoice
Exhibit C*	General Terms and Conditions ( <a href="http://www.ols.dgs.ca.gov/Standard+Language">http://www.ols.dgs.ca.gov/Standard+Language</a> )
Exhibit D(S)	Special Terms and Conditions
Exhibit E	Additional Provisions
Exhibit F	HIPAA Business Associate Addendum
Exhibit G	Contractor's Release
Exhibit H	Inventory/Disposition of CDPH Funded Equipment

## INSTRUCTIONS FOR COMPLETION OF APPLICATION PACKAGE

1. The Vendor Information form must be typed or printed.
2. If additional space is needed to complete a response to any portion of the Application, attach an additional sheet of paper and identify it by including the title of the required document at the top of the page.
3. The application package and enclosed vendor Exhibits are attached for your review and approval. Complete and sign the Application package and affix signature on the face of the agreement for a fully executed vendor agreement.
4. Documents may be submitted via e-mail to: [MJaavaid@cdph.ca.gov](mailto:MJaavaid@cdph.ca.gov) or via fax to (510) 620-6258, attention Muslimah Jaavaid. Items that require a signature if e-mailed or faxed must be followed with an original signed copy.
5. The Genetic Disease Screening Program, Newborn Screening Program must receive two (2) copies of the completed and signed Application package and two (2) copies of the signed vendor agreement by October 14, 2011. Please submit the required documents to:

Muslimah Jaavaid, Contract Manager  
California Department of Public Health  
Genetic Disease Screening Program  
850 Marina Bay Parkway,  
Rm. F175, Mail Stop 8200  
Richmond, CA 94804

### NOTE:

**Failure to return a completed and signed Application package and signed vendor agreement, by the due date, will result in a delay of the execution of your vendor agreement and is subject to budget changes.**

**HEMOGLOBIN REFERENCE LABORATORY VENDOR INFORMATION**

1. LEGAL NAME OF AGENCY AND ADDRESS (as it is to appear on agreement):

Name: Children's Hospital & Research Center at Oakland

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Address:

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City: Oakland

Zip: 94609

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2. Federal Tax ID Number \_\_\_\_\_

Agency Tax Status:  Public (Government/University)  Nonprofit  Private

3. **Project/Medical Director** (The Project Director will receive all programmatic, budgetary and accounting correspondence for the project and will be responsible for the proper dissemination of project information and overall clinic coordination):

Name:

Title:

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Address:

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City:

Zip:

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Telephone:

Fax:

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Email:

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4. **Laboratory Supervisor** (Under the direction of the Project Director, this person is responsible for ongoing daily NBS follow-up activities and assuring the data on case follow-up is entered in the NBS Screening Information System (SIS) in a timely manner):

Name: Mahin Azimi, CLS

Title: Sr. Clinical Laboratory  
Scientist

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Address: Children's Hospital & Research Center at Oakland  
747 52<sup>nd</sup> Street, Oakland, CA 94609-1809

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City: Oakland

Zip: 94609

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Telephone: (510) 450-7688

Fax: (510) 601-3928

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Email: mazimi@chori.org

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**HEMOGLOBIN REFERENCE LABORATORY VENDOR INFORMATION****5. HEMOGLOBIN REFERENCE LABORATORY STAFF**

Licensed Clinical Laboratory Scientist:

Helen Lee, CLS

Phone: \_\_\_\_\_

Email: hlee@chori.org  
\_\_\_\_\_**Other Laboratory Staff**

Name &amp; Title: \_\_\_\_\_

Phone: \_\_\_\_\_

Email: \_\_\_\_\_

Name &amp; Title: \_\_\_\_\_

Phone: \_\_\_\_\_

Email: \_\_\_\_\_

**6. Agency Official** (This person has official signature authority to enter into an agreement for the agency.):**Name:** \_\_\_\_\_**Title:** \_\_\_\_\_**Address:** \_\_\_\_\_**City:** \_\_\_\_\_**Zip:** \_\_\_\_\_**Telephone:** \_\_\_\_\_**Fax:** \_\_\_\_\_**Email:** \_\_\_\_\_**7.** All payments for invoices are automatically sent to the address of the Agency Official. If the address of the Agency Official is not the address to which payments should be mailed, please indicate the correct contact person and address below:**Name:** \_\_\_\_\_**Title:** \_\_\_\_\_**Address:** \_\_\_\_\_**City:** \_\_\_\_\_**Zip:** \_\_\_\_\_**Telephone:** \_\_\_\_\_**Fax:** \_\_\_\_\_**Email:** \_\_\_\_\_

**HEMOGLOBIN REFERENCE LABORATORY VENDOR INFORMATION**

**8. REQUIRED ITEMS FOR SUBMISSION**

Please place an "X" on each line to indicate that the documents listed below have been submitted.

- (1) Vendor Information (Attachment 1) \_\_\_\_\_
- (2) Payee Data Record (Attachment 2) \_\_\_\_\_
- (3) Contractor Certification Clause (Attachment 3) \_\_\_\_\_
- (4) Darfur Contracting Act (Attachment 4) \_\_\_\_\_
- (5) Standard Agreement \_\_\_\_\_  
 (2 original signed face sheets)

The undersigned hereby affirms that the statements contained in the application are true and complete to the best of the applicant's knowledge and accepts as a condition of the agreement the obligation to comply with the applicable State and Federal requirements, policies, standards and regulations. **The undersigned recognizes that this is a public document and open to public inspection.**

\_\_\_\_\_  
Signature of Agency Official

\_\_\_\_\_  
Title

\_\_\_\_\_  
Date

**PAYEE DATA RECORD**

(Required when receiving payment from the State of California in lieu of IRS W-9)  
 STD. 204 (Rev. 5/06)\_CDPH

<b>1</b>	<p><b>INSTRUCTIONS:</b> Complete all information on this form. Sign, date, and return to the State agency (department/office) address shown at the bottom of this page. Prompt return of this <b>fully completed</b> form will prevent delays when processing payments. Information provided in this form will be used by State agencies to prepare Information Returns (1099). See reverse side for more information and Privacy Statement.</p> <p><b>NOTE:</b> Governmental entities, federal, state, and local (including school districts), are not required to submit this form.</p>								
<b>2</b>	<p>PAYEE'S LEGAL BUSINESS NAME (Type or Print)</p> <hr/> <table style="width:100%; border:none;"> <tr> <td style="width:50%; border:none;">SOLE PROPRIETOR—ENTER NAME AS SHOWN ON SSN (Last, First, M.I.)</td> <td style="width:50%; border:none;">E-MAIL ADDRESS</td> </tr> <tr> <td style="border:none;">MAILING ADDRESS</td> <td style="border:none;">BUSINESS ADDRESS</td> </tr> <tr> <td style="border:none;">CITY, STATE, ZIP CODE</td> <td style="border:none;">CITY, STATE, ZIP CODE</td> </tr> </table>			SOLE PROPRIETOR—ENTER NAME AS SHOWN ON SSN (Last, First, M.I.)	E-MAIL ADDRESS	MAILING ADDRESS	BUSINESS ADDRESS	CITY, STATE, ZIP CODE	CITY, STATE, ZIP CODE
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MAILING ADDRESS	BUSINESS ADDRESS								
CITY, STATE, ZIP CODE	CITY, STATE, ZIP CODE								
<b>3</b>	<p><b>ENTER FEDERAL EMPLOYER IDENTIFICATION NUMBER (FEIN):</b> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/></p> <p><b>CHECK ONE BOX ONLY</b></p> <table style="width:100%; border:none;"> <tr> <td style="width:30%; vertical-align:top;"> <input type="checkbox"/> <b>PARTNERSHIP</b>   <input type="checkbox"/> <b>ESTATE OR TRUST</b>   <input type="checkbox"/> <b>INDIVIDUAL OR SOLE PROPRIETOR</b>  <b>ENTER SOCIAL SECURITY NUMBER:</b> </td> <td style="width:70%; vertical-align:top;"> <p><b>CORPORATION:</b></p> <input type="checkbox"/> <b>MEDICAL</b> (e.g., dentistry, psychotherapy, chiropractic, etc.)  <input type="checkbox"/> <b>LEGAL</b> (e.g., attorney services)  <input type="checkbox"/> <b>EXEMPT</b> (nonprofit)  <input type="checkbox"/> <b>ALL OTHERS</b> <hr/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <p style="text-align:center; font-size:small;">(SSN required by authority of California Revenue and Tax Code Section 18646)</p> </td> </tr> </table>	<input type="checkbox"/> <b>PARTNERSHIP</b>  <input type="checkbox"/> <b>ESTATE OR TRUST</b>  <input type="checkbox"/> <b>INDIVIDUAL OR SOLE PROPRIETOR</b> <b>ENTER SOCIAL SECURITY NUMBER:</b>	<p><b>CORPORATION:</b></p> <input type="checkbox"/> <b>MEDICAL</b> (e.g., dentistry, psychotherapy, chiropractic, etc.) <input type="checkbox"/> <b>LEGAL</b> (e.g., attorney services) <input type="checkbox"/> <b>EXEMPT</b> (nonprofit) <input type="checkbox"/> <b>ALL OTHERS</b> <hr/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <p style="text-align:center; font-size:small;">(SSN required by authority of California Revenue and Tax Code Section 18646)</p>	<p><b>NOTE:</b>                  Payment will not be processed without an accompanying taxpayer I.D. number.</p>					
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<b>4</b>	<p><b>PAYEE RESIDENCY TYPE</b></p> <input type="checkbox"/> California resident—qualified to do business in California or maintains a permanent place of business in California. <input type="checkbox"/> California nonresident (see reverse side)—Payments to nonresidents for services may be subject to State income tax withholding. <input type="checkbox"/> No services performed in California. <input type="checkbox"/> Copy of Franchise Tax Board waiver of State withholding attached.								
<b>5</b>	<p style="text-align:center;"><b>I hereby certify under penalty of perjury that the information provided on this document is true and correct. Should my residency status change, I will promptly notify the State agency below.</b></p> <table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td style="width:50%;">AUTHORIZED PAYEE REPRESENTATIVE'S NAME (Type or Print)</td> <td colspan="2">TITLE</td> </tr> <tr> <td>SIGNATURE</td> <td>DATE</td> <td>TELEPHONE (    )</td> </tr> </table>			AUTHORIZED PAYEE REPRESENTATIVE'S NAME (Type or Print)	TITLE		SIGNATURE	DATE	TELEPHONE (    )
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SIGNATURE	DATE	TELEPHONE (    )							
<b>6</b>	<p><b>Please return completed form to:</b></p> <p><b>Department/Office:</b> <u>California Department of Public Health</u></p> <p><b>Unit/Section:</b> <u>Family Center for Health/Genetic Disease Screening Program Attn: Muslimah Jaavaid</u></p> <p><b>Mailing Address:</b> <u>850 Marina Bay Parkway, Room F175, Mail Stop 8200</u></p> <p><b>City/State/ZIP:</b> <u>Richmond, CA 94804</u></p> <p><b>Telephone:</b> <u>( 510 ) 412-1476</u>      <b>FAX:</b> <u>( 510 ) 620-6258</u></p> <p><b>E-Mail Address:</b> <u>M.Jaavaid@cdph.ca.gov</u></p>								

**PAYEE DATA RECORD**

STD. 204 (Rev. 5/06)\_CDPH (Page 2)

1	<p><b>Requirement to Complete Payee Data Record, STD. 204</b></p> <p>A completed Payee Data Record, STD. 204, is required for payments to all non-governmental entities and will be kept on file at each State agency. Since each State agency with which you do business must have a separate STD. 204 on file, it is possible for a payee to receive this form from various State agencies.</p> <p>Payees who do not wish to complete the STD. 204 may elect to not do business with the State. If the payee does not complete the STD. 204 and the required payee data is not otherwise provided, payment may be reduced for federal backup withholding and nonresident State income tax withholding. Amounts reported on Information Returns (1099) are in accordance with the Internal Revenue Code and the California Revenue and Taxation Code.</p>						
2	<p>Enter the payee's legal business name. Sole proprietorships must also include the owner's full name. An individual must list his/her full name. The mailing address should be the address at which the payee chooses to receive correspondence. Do not enter payment address or lock box information here.</p>						
3	<p>Check the box that corresponds to the payee business type. Check only one box. Corporations must check the box that identifies the type of corporation. The State of California requires that all parties entering into business transactions that may lead to payment(s) from the State provide their Taxpayer Identification Number (TIN). The TIN is required by the California Revenue and Taxation Code Section 18646 to facilitate tax compliance enforcement activities and the preparation of Form 1099 and other information returns as required by the Internal Revenue Code Section 6109(a).</p> <p>The TIN for individuals and sole proprietorships is the Social Security Number (SSN). Only partnerships, estates, trusts, and corporations will enter their Federal Employer Identification Number (FEIN).</p>						
4	<p><b><u>Are you a California resident or nonresident?</u></b></p> <p>A corporation will be defined as a "resident" if it has a permanent place of business in California or is qualified through the Secretary of State to do business in California.</p> <p>A partnership is considered a resident partnership if it has a permanent place of business in California. An estate is a resident if the decedent was a California resident at time of death. A trust is a resident if at least one trustee is a California resident.</p> <p>For individuals and sole proprietors, the term "resident" includes every individual who is in California for other than a temporary or transitory purpose and any individual domiciled in California who is absent for a temporary or transitory purpose. Generally, an individual who comes to California for a purpose that will extend over a long or indefinite period will be considered a resident. However, an individual who comes to perform a particular contract of short duration will be considered a nonresident.</p> <p>Payments to all nonresidents may be subject to withholding. Nonresident payees performing services in California or receiving rent, lease, or royalty payments from property (real or personal) located in California will have 7% of their total payments withheld for State income taxes. However, no withholding is required if total payments to the payee are \$1,500 or less for the calendar year.</p> <p>For information on Nonresident Withholding, contact the Franchise Tax Board at the numbers listed below:</p> <table border="0" data-bbox="155 1325 1414 1381"> <tr> <td>Withholding Services and Compliance Section:</td> <td>1-888-792-4900</td> <td>E-mail address: <a href="mailto:wscs.gen@ftb.ca.gov">wscs.gen@ftb.ca.gov</a></td> </tr> <tr> <td>For hearing impaired with TDD, call:</td> <td>1-800-822-6268</td> <td>Website: <a href="http://www.ftb.ca.gov">www.ftb.ca.gov</a></td> </tr> </table>	Withholding Services and Compliance Section:	1-888-792-4900	E-mail address: <a href="mailto:wscs.gen@ftb.ca.gov">wscs.gen@ftb.ca.gov</a>	For hearing impaired with TDD, call:	1-800-822-6268	Website: <a href="http://www.ftb.ca.gov">www.ftb.ca.gov</a>
Withholding Services and Compliance Section:	1-888-792-4900	E-mail address: <a href="mailto:wscs.gen@ftb.ca.gov">wscs.gen@ftb.ca.gov</a>					
For hearing impaired with TDD, call:	1-800-822-6268	Website: <a href="http://www.ftb.ca.gov">www.ftb.ca.gov</a>					
5	<p>Provide the name, title, signature, and telephone number of the individual completing this form. Provide the date the form was completed.</p>						
6	<p>This section must be completed by the State agency requesting the STD. 204.</p>						

**Privacy Statement**

Section 7(b) of the Privacy Act of 1974 (Public Law 93-579) requires that any federal, State, or local governmental agency, which requests an individual to disclose their social security account number, shall inform that individual whether that disclosure is mandatory or voluntary, by which statutory or other authority such number is solicited, and what uses will be made of it.

It is mandatory to furnish the information requested. Federal law requires that payment for which the requested information is not provided is subject to federal backup withholding and State law imposes noncompliance penalties of up to \$20,000.

You have the right to access records containing your personal information, such as your SSN. To exercise that right, please contact the business services unit or the accounts payable unit of the State agency(ies) with which you transact that business.

All questions should be referred to the requesting State agency listed on the bottom front of this form.

CCC-307

**CERTIFICATION**

I, the official named below, CERTIFY UNDER PENALTY OF PERJURY that I am duly authorized to legally bind the prospective Contractor to the clause(s) listed below. This certification is made under the laws of the State of California.

<i>Contractor/Bidder Firm Name (Printed)</i>		<i>Federal ID Number</i>
<i>By (Authorized Signature)</i>		
<i>Printed Name and Title of Person Signing</i>		
<i>Date Executed</i>	<i>Executed in the County of</i>	

**CONTRACTOR CERTIFICATION CLAUSES**

1. **STATEMENT OF COMPLIANCE:** Contractor has, unless exempted, complied with the nondiscrimination program requirements. (Gov. Code §12990 (a-f) and CCR, Title 2, Section 8103) (Not applicable to public entities.)

2. **DRUG-FREE WORKPLACE REQUIREMENTS:** Contractor will comply with the requirements of the Drug-Free Workplace Act of 1990 and will provide a drug-free workplace by taking the following actions:

a. Publish a statement notifying employees that unlawful manufacture, distribution, dispensation, possession or use of a controlled substance is prohibited and specifying actions to be taken against employees for violations.

b. Establish a Drug-Free Awareness Program to inform employees about:

1) the dangers of drug abuse in the workplace;

2) the person's or organization's policy of maintaining a drug-free workplace;

3) any available counseling, rehabilitation and employee assistance programs; and,

4) penalties that may be imposed upon employees for drug abuse violations.

c. Every employee who works on the proposed Agreement will:

- 1) receive a copy of the company's drug-free workplace policy statement; and,
- 2) agree to abide by the terms of the company's statement as a condition of employment on the Agreement.

Failure to comply with these requirements may result in suspension of payments under the Agreement or termination of the Agreement or both and Contractor may be ineligible for award of any future State agreements if the department determines that any of the following has occurred: the Contractor has made false certification, or violated the certification by failing to carry out the requirements as noted above. (Gov. Code §8350 et seq.)

3. NATIONAL LABOR RELATIONS BOARD CERTIFICATION: Contractor certifies that no more than one (1) final unappealable finding of contempt of court by a Federal court has been issued against Contractor within the immediately preceding two-year period because of Contractor's failure to comply with an order of a Federal court, which orders Contractor to comply with an order of the National Labor Relations Board. (Pub. Contract Code §10296) (Not applicable to public entities.)

4. CONTRACTS FOR LEGAL SERVICES \$50,000 OR MORE- PRO BONO REQUIREMENT: Contractor hereby certifies that contractor will comply with the requirements of Section 6072 of the Business and Professions Code, effective January 1, 2003.

Contractor agrees to make a good faith effort to provide a minimum number of hours of pro bono legal services during each year of the contract equal to the lessor of 30 multiplied by the number of full time attorneys in the firm's offices in the State, with the number of hours prorated on an actual day basis for any contract period of less than a full year or 10% of its contract with the State.

Failure to make a good faith effort may be cause for non-renewal of a state contract for legal services, and may be taken into account when determining the award of future contracts with the State for legal services.

5. EXPATRIATE CORPORATIONS: Contractor hereby declares that it is not an expatriate corporation or subsidiary of an expatriate corporation within the meaning of Public Contract Code Section 10286 and 10286.1, and is eligible to contract with the State of California.

6. SWEATFREE CODE OF CONDUCT:

a. All Contractors contracting for the procurement or laundering of apparel, garments or corresponding accessories, or the procurement of equipment, materials, or supplies, other than procurement related to a public works contract, declare under penalty of perjury that

no apparel, garments or corresponding accessories, equipment, materials, or supplies furnished to the state pursuant to the contract have been laundered or produced in whole or in part by sweatshop labor, forced labor, convict labor, indentured labor under penal sanction, abusive forms of child labor or exploitation of children in sweatshop labor, or with the benefit of sweatshop labor, forced labor, convict labor, indentured labor under penal sanction, abusive forms of child labor or exploitation of children in sweatshop labor. The contractor further declares under penalty of perjury that they adhere to the Sweatfree Code of Conduct as set forth on the California Department of Industrial Relations website located at [www.dir.ca.gov](http://www.dir.ca.gov), and Public Contract Code Section 6108.

b. The contractor agrees to cooperate fully in providing reasonable access to the contractor's records, documents, agents or employees, or premises if reasonably required by authorized officials of the contracting agency, the Department of Industrial Relations, or the Department of Justice to determine the contractor's compliance with the requirements under paragraph (a).

7. DOMESTIC PARTNERS: For contracts over \$100,000 executed or amended after January 1, 2007, the contractor certifies that contractor is in compliance with Public Contract Code section 10295.3.

### **DOING BUSINESS WITH THE STATE OF CALIFORNIA**

The following laws apply to persons or entities doing business with the State of California.

1. CONFLICT OF INTEREST: Contractor needs to be aware of the following provisions regarding current or former state employees. If Contractor has any questions on the status of any person rendering services or involved with the Agreement, the awarding agency must be contacted immediately for clarification.

Current State Employees (Pub. Contract Code §10410):

1). No officer or employee shall engage in any employment, activity or enterprise from which the officer or employee receives compensation or has a financial interest and which is sponsored or funded by any state agency, unless the employment, activity or enterprise is required as a condition of regular state employment.

2). No officer or employee shall contract on his or her own behalf as an independent contractor with any state agency to provide goods or services.

Former State Employees (Pub. Contract Code §10411):

1). For the two-year period from the date he or she left state employment, no former state officer or employee may enter into a contract in which he or she engaged in any of the

negotiations, transactions, planning, arrangements or any part of the decision-making process relevant to the contract while employed in any capacity by any state agency.

2). For the twelve-month period from the date he or she left state employment, no former state officer or employee may enter into a contract with any state agency if he or she was employed by that state agency in a policy-making position in the same general subject area as the proposed contract within the 12-month period prior to his or her leaving state service.

If Contractor violates any provisions of above paragraphs, such action by Contractor shall render this Agreement void. (Pub. Contract Code §10420)

Members of boards and commissions are exempt from this section if they do not receive payment other than payment of each meeting of the board or commission, payment for preparatory time and payment for per diem. (Pub. Contract Code §10430 (e))

2. LABOR CODE/WORKERS' COMPENSATION: Contractor needs to be aware of the provisions which require every employer to be insured against liability for Worker's Compensation or to undertake self-insurance in accordance with the provisions, and Contractor affirms to comply with such provisions before commencing the performance of the work of this Agreement. (Labor Code Section 3700)

3. AMERICANS WITH DISABILITIES ACT: Contractor assures the State that it complies with the Americans with Disabilities Act (ADA) of 1990, which prohibits discrimination on the basis of disability, as well as all applicable regulations and guidelines issued pursuant to the ADA. (42 U.S.C. 12101 et seq.)

4. CONTRACTOR NAME CHANGE: An amendment is required to change the Contractor's name as listed on this Agreement. Upon receipt of legal documentation of the name change the State will process the amendment. Payment of invoices presented with a new name cannot be paid prior to approval of said amendment.

5. CORPORATE QUALIFICATIONS TO DO BUSINESS IN CALIFORNIA:

a. When agreements are to be performed in the state by corporations, the contracting agencies will be verifying that the contractor is currently qualified to do business in California in order to ensure that all obligations due to the state are fulfilled.

b. "Doing business" is defined in R&TC Section 23101 as actively engaging in any transaction for the purpose of financial or pecuniary gain or profit. Although there are some statutory exceptions to taxation, rarely will a corporate contractor performing within the state not be subject to the franchise tax.

c. Both domestic and foreign corporations (those incorporated outside of California) must be in good standing in order to be qualified to do business in California. Agencies will

determine whether a corporation is in good standing by calling the Office of the Secretary of State.

6. RESOLUTION: A county, city, district, or other local public body must provide the State with a copy of a resolution, order, motion, or ordinance of the local governing body which by law has authority to enter into an agreement, authorizing execution of the agreement.

7. AIR OR WATER POLLUTION VIOLATION: Under the State laws, the Contractor shall not be: (1) in violation of any order or resolution not subject to review promulgated by the State Air Resources Board or an air pollution control district; (2) subject to cease and desist order not subject to review issued pursuant to Section 13301 of the Water Code for violation of waste discharge requirements or discharge prohibitions; or (3) finally determined to be in violation of provisions of federal law relating to air or water pollution.

8. PAYEE DATA RECORD FORM STD. 204: This form must be completed by all contractors that are not another state agency or other governmental entity.

## Darfur Contracting Act

Pursuant to Public Contract Code (PCC) sections 10475-10481, the Darfur Contracting Act's intent is to preclude State agencies from contracting with scrutinized companies that do business in the African nation of Sudan. A scrutinized company is a company doing specified types of business in Sudan as defined in PCC section 10476. Scrutinized companies are ineligible to, and cannot, contract with a State agency for goods or services (PCC section 10477(a)) unless obtaining permission from the Department of General Services according to the criteria set forth in PCC section 10477(b).

Therefore, to be eligible to contract with the California Department of Public Health, please initial **one of the following** three paragraphs and complete the certification below:

1.        \_\_\_\_\_  
          Initials            We do not currently have, or we have not had within the previous three years, business activities or other operations outside of the United States.

**OR**

2.        \_\_\_\_\_  
          Initials            We are a scrutinized company as defined in Public Contract Code section 10476, but we have received written permission from the Department of General Services (DGS) to submit a bid or proposal pursuant to Public Contract Code section 10477(b) or submit a contract/purchase order. A copy of the written permission from DGS is included with our bid, proposal or contract/purchase order.

**OR**

3.        \_\_\_\_\_  
          Initials            We currently have, or we have had within the previous three years, business activities or other operations outside of the United States, but we certify below that we are not a scrutinized company as defined in Public Contract Code section 10476.

**CERTIFICATION**

I, the official named below, CERTIFY UNDER PENALTY OF PERJURY that I am duly authorized to legally bind this company to the clause listed above. This certification is made under the laws of the State of California.

<i>Company Name (Printed)</i>	<i>Federal ID Number</i>
<i>By (Authorized Signature)</i>	
<i>Printed Name and Title of Person Signing</i>	
<i>Date Executed</i>	<i>Executed in the County and State of</i>

**GENETIC DISEASE SCREENING PROGRAM, NEWBORN SCREENING PROGRAM  
VENDOR AGREEMENT WITH HEMOGLOBIN REFERENCE LABORATORY**

1. **Purpose of agreement:** This agreement is entered into between California Department of Public Health (CDPH) hereafter referred to as the State, and Children's Hospital & Research Center at Oakland, hereafter referred to as the vendor.
2. The term of this agreement is July 1, 2011 through June 30, 2012:
3. The parties agree to comply with the terms and conditions of the following exhibits, which are by this reference made a part of this Agreement.

Exhibit A – Scope of Work	8 pages
Exhibit A – Attachment I - Quarterly Summary Report	4 pages
Exhibit B – Budget Detail and Payment Provisions	3 pages
Exhibit B – Attachment I – Vendor Payment Provisions	1 page
Exhibit B – Attachment II – Sample Invoice	1 page
Exhibit C* - General Terms and Conditions	<u>GTC 610</u>
Exhibit D(S) – Special Terms and Conditions (Attached hereto as part of this agreement)	18 pages
Notwithstanding provisions 1, 4, 9, 11, 14, 15,16, 18, 19, 20 which does not apply to this agreement	
Exhibit E – Additional Provisions	3 pages
Exhibit F – HIPAA Business Associate Exhibit	12 pages
Exhibit G - Contractor Release	1 page
Exhibit H– Inventory/Disposition of CDPH-Funded Equipment	2 pages

Items shown above with an Asterisk (\*), are hereby incorporated by reference and made part of this agreement as if attached hereto. These documents can be viewed at <http://www.ols.dgs.ca.gov/Standard+Language>.

**IN WITNESS WHEREOF, this Agreement has been executed by the parties hereto.**

<b>VENDOR</b>				
VENDOR'S NAME Children's Hospital & Research Center at Oakland				
BY (Authorized Signature)			DATE SIGNED (Do not type)	
PRINTED NAME AND TITLE OF PERSON SIGNING Bertram Lubin, MD., President and CEO				
ADDRESS 5700 Martin Luther King Jr. Way, Oakland., CA. 94609				
<b>STATE OF CALIFORNIA</b>				
AGENCY NAME California Department of Public Health, Genetic Disease Screening Program				
BY (Authorized Signature)			DATE SIGNED (Do not type)	
PRINTED NAME AND TITLE OF PERSON SIGNING Leslie Gaffney, Assistant Division Chief, Genetic Disease Screening Program				
ADDRESS 850 Marina Bay Parkway, Room F-175, Mail Stop 8200, Richmond, CA 94804				
FUND NUMBER AND NAME 5530 Genetic Disease Fund	ITEM 4265-111-0203	FISCAL YEAR 2011/2012	CHAPTER 33	STATUTE 2011/2012
OBJECT OF EXPENDITURE (CODE AND TITLE) 11-53204-5530-418-02				

**Exhibit A**  
Scope of Work

**1. Service Overview**

Vendor agrees to provide to the State of California Department of Public Health (CDPH), Genetic Disease Screening Program (GDSP) the services described herein.

The purpose of the vendor agreement is to provide confirmatory testing of infants with Newborn Screening (NBS) results that are positive for a potentially significant hemoglobinopathy. Confirmatory testing includes testing the parents whose results are necessary to confirm the infant's NBS results.

**2. Service Location**

The services shall be performed at:

5700 Martin Luther King Jr. Way  
Oakland, CA 94609-1673.

**3. Service Hours**

The services shall be provided during normal Vendor working hours, but at a minimum of Monday through Friday, 8:00 am – 5:00 pm, excluding state holidays.

**4. Project Representatives**

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

<b>California Department of Public Health</b>  Administrator  Muslimah Jaavaid Telephone: (510) 412-1476 Fax: (510) 620-6258 Email: <a href="mailto:M.Jaavaid@cdph.ca.gov">M.Jaavaid@cdph.ca.gov</a>	<b>Children's Hospital &amp; Research Center at Oakland</b>  Project Director: Bertram Lubin, MD, President and CEO 5700 Martin Luther King Jr. Way Oakland, CA 94609-1673 Telephone: (510) 450-7600 Fax: (510) 450-7910 Email: <a href="mailto:BLubin@mail.cho.org">BLubin@mail.cho.org</a>
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B. Direct all inquiries to:

<b>California Department of Public Health</b> NBSP Hemoglobin Reference Lab Vendor Liaison: Genetic Disease Screening Program Attention: Shellye Lessing, MS 850 Marina Bay Parkway, F175, MS 8200 Telephone: (510) 412-1487 Fax : (510) 412-1552 Email : <a href="mailto:Shellye.Lessing@cdph.ca.gov">Shellye.Lessing@cdph.ca.gov</a>	<b>Children's Hospital &amp; Research Center at Oakland</b>  Contract Manager: Rebecca Rosales 5700 Martin Luther King Jr. Way Oakland, CA 94609-1673 Telephone: (510) 450-7698 Fax: (510) 450-7973 Email: <a href="mailto:Rrosales@chori.org">Rrosales@chori.org</a>
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**Exhibit A**  
Scope of Work

- C. Either party may make changes to the information above by giving written notice to the other party within 30 days of the anticipated change. Said changes shall not require an amendment to this vendor agreement.

**5. Services to be Performed**

The Vendor shall perform the following services:

**A. Confirmatory Testing for Hemoglobin Disease Positive Newborn Screening Results**

As a hemoglobin confirmatory laboratory for follow-up of initial positive screening results consistent with a potentially clinically significant hemoglobin disorder, the Vendor shall provide CDPH with hemoglobin confirmatory testing on blood specimens from infants born in California whose screening results are defined as indicative of a potentially significant hemoglobinopathy; and on blood specimens from the parents of newborns, whose results are necessary to confirm the screening results. Initial NBS positive results include but are not limited to hemoglobin patterns of F, FS, FSa, FSC, FSD, FSE, FSV, where V means an unknown variant hemoglobin, FE, FV, FC, FCa, FD, FDa, FEa; patterns with four hemoglobins if A is absent; patterns including an amount of Hb Barts above the cutoff for Hemoglobin H disease; and newborns who were transfused prior to NBS collection who have a hemoglobin pattern containing one or more hemoglobin variants.

1. Provide the Newborn Screening Program Area Service Centers (ASCs) with instructions for proper collection of hemoglobin confirmatory specimens.
2. Receive specimens from ASCs, newborn's physician, hospital, or California Children's Services (CCS)-approved Sickle Cell Disease Centers. Notify the ASC of receipt of specimens.
3. Analyze hemoglobin confirmatory specimens within ten (10) working days of receipt using the following methods:
  - a. Separation of hemoglobins F, A, S, C, D and E with relative concentrations for each hemoglobin on all specimens by cellulose acetate-citrate agar electrophoresis, isoelectric focusing, high pressure liquid chromatography, and/or DNA analysis as approved by the CDPH.
  - b. Provide a hemogram on each suitable specimen to include hemoglobin, red blood cell count (RBC), mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH) and red cell distribution width (RDW).
  - c. Perform Free Erythrocyte Protoporphyrin (FEP) on specimens with microcytic hypochromic anemia.
  - d. Provide quantitative hemoglobin A2 when necessary to resolve phenotype.

**Exhibit A**  
Scope of Work

- e. Provide quantitative hemoglobin F when necessary to resolve phenotype.
4. Provide DNA analysis to differentiate between EE and E/Beta thalassemia, to detect beta thalassemia mutations in newborns with results of FS, FC, or FD in the absence of one parent, to identify the beta thalassemia mutation in the infant when one parent has elevated Hb A2, and to examine inconsistencies between thin layer isoelectric focusing profiles of newborn and parents. Provide beta globin DNA analysis for infants with an NBS pattern of "FSa", "FCa", "FDa" and "FEa" to confirm a beta+ thalassemia mutation.
5. Provide CDPH with DNA analysis for alpha globin deletions and other point mutations on samples from infants with Barts Hb above the cutoff for Hb H disease on the NBS within fifteen (15) business days of receipt of specimen.
6. Provide CDPH with analysis for unusual Hb variants such as: Hb Korle Bu, HB T Cambodian, Hb Matsue-Okie, Hb O Arab, Hb C Harlem, Hb G Philadelphia, Hb Constant Spring carried in compound heterozygosity with clinically significant hemoglobin variants (including but not limited to Hb S, C, E mutations, beta thalassemia, or Hb Barts) or as only the adult hemoglobin (FV pattern). DNA studies for Hb Constant Spring will be completed within fifteen (15) business days of receipt of specimen. Presumptive findings for and the presumptive diagnosis for Hb Korle Bu, HB T Cambodian, Hb Matsue-Okie, Hb O Arab, Hb C Harlem, Hb G Philadelphia will be completed and reported within thirty (30) days, and final determination within ninety (90) days of receipt of specimen. Any deviations in timeframe will be reported and explained to the CDPH.
7. Provide CDPH with analysis of unknown rare variants carried in compound heterozygosity with clinically significant hemoglobin variants (including but not limited to Hb S, C, E mutations, beta thalassemia, or Hb Barts) or as only the adult hemoglobin within ninety days (90) days of receipt of specimen.
8. Report initial and any subsequent test results to the ASC and to Genetic Disease Screening Program (GDSP) within twenty-four (24) hours of completion of the test; enter test result into the GDSP's internet-based computerized Screening Information System (SIS). Provide a written report of test results, interpretations of results and recommendations for follow-up to the ASC with a copy to GDSP. The test results report must list the telephone number at which physicians can obtain hematological consultation. The report of test results must be typewritten with no handwritten notes or crossed out words. If a report subsequently requires an amendment or correction, a new report will be issued and labeled as amended or corrected. A dated addendum may be added to the initial report. Additional or new interpretation or recommendations must be reviewed, signed and dated by the hematologist.
9. The Vendor shall provide consultation upon request to referring physicians, to ASCs and Newborn Screening Branch (NBSB) staff regarding interpretations of laboratory data, family history or other information necessary to provide accurate diagnosis or

**Exhibit A**  
Scope of Work

reproductive risk counseling to families referred as a result of the California Newborn Screening Program.

10. Test hemoglobin confirmatory specimens using the tests, including DNA analyses, which, after consultation with newborn's physicians or the Medical Director of the ASC, are determined necessary for accurate counseling.
11. Reports on patterns containing a hemoglobin variant(s) must state when a final determination will be completed, not to exceed ninety (90) days from receipt of specimen. Interim or incomplete information on the variant(s) should be reported if known.
12. Recommend additional appropriate laboratory tests necessary for accurate counseling or diagnosis.

**B. Follow-up Testing for Hemoglobin Results of Unknown Significance on Newborn Screening (Follow-up requested by primary care provider)**

As a hemoglobin consultation laboratory, Vendor shall provide, after appropriate consultation with newborn's physician, any tests on specimens from newborns or their families where additional testing is authorized by the CDPH based on unusual newborn screening patterns, including, but not limited to FCD, FCE, FCV, FDC, FDE, FDV, FEC, FED, FEV, FVC, FVD, FVE, FVV; patterns of four hemoglobins with A present, newborns transfused prior to screening, and patterns of FAV or FVA.

**C. Follow-up Testing for Families of Newborns with Hb S, C, or D Trait**

As a hemoglobin reference laboratory for hemoglobin carrier trait follow-up, Vendor shall provide CDPH with hemoglobin testing on blood specimens from families of newborns born in California whose screening results have been defined by CDPH as carriers of sickling and other specific hemoglobins. These patterns include, but are not limited to FAS, FAC, FAD, FSA, FCA, FDA, and results of AFS, AFC or AFD in older babies. Vendor shall provide testing to parents, siblings and other family members of the screened newborn upon receipt of blood samples submitted by the newborn's physician, hospital, outpatient lab, CCS-approved Sickle Cell Disease Center or Sickle Cell Trait Follow-up Program-contracted phlebotomy sites accompanied by a Newborn Screening Hemoglobin Trait Lab Intake form. If a confirmatory specimen is submitted on the newborn it shall also be tested.

1. Provide the NBS Sickle Cell Trait Counselor or other sites at the request of the counselor with instructions for proper collection of hemoglobin confirmatory specimens.
2. Receive specimens from the newborn's physician, hospital or outpatient lab, Sickle Cell Trait Follow-up Program-contracted phlebotomy sites or CCS-approved Sickle Cell Disease Center.
3. Analyze specimens referred as part of carrier trait follow-up within ten (10) working days of receipt using the following methods:

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Scope of Work

- a. Separation of hemoglobins F, A, S, C, D, and E with relative concentrations for each hemoglobin on all specimens by cellulose acetate-citrate agar electrophoresis, isoelectric focusing, high pressure liquid chromatography, and/or DNA analysis as approved by the CDPH.
  - b. Provide a hemogram on each suitable specimen, to include hemoglobin, hematocrit, mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH) and red cell distribution width (RDW).
  - c. Perform Free Erythrocyte Protoporphyrin (FEP) on specimens with microcytic hypochromic anemia.
  - d. Provide quantitative hemoglobin A2 when necessary to resolve phenotype or genotype.
  - e. Provide quantitative hemoglobin F when necessary to resolve phenotype or genotype.
  - f. Provide DNA analysis when necessary to resolve phenotype or genotype.
4. Report test results to the NBS Sickle Cell Trait Counselor at the GDSP within twenty-four (24) hours of completion of the test; enter test results into the GDSP's Screening Information System (SIS) program. Provide a faxed copy of the written report of test results, interpretations of results and recommendations for follow-up to the GDSP and hard copies of the reports to the Sickle Cell Trait Follow-up Program Coordinator. The test results report must list the telephone number at which physicians can obtain hematological consultation. The report of test results must be typewritten with no handwritten notes or crossed out words. If a report subsequently requires an amendment or correction, a new report will be issued and labeled as amended or corrected. A dated addendum may be added to the initial report. Additional or new interpretation or recommendations must be reviewed, signed and dated by the hematologist.
  5. Provide the NBS Sickle Cell Trait Counselor at the GDSP with analysis of an unknown rare variant trait in a parent when the other parent is a carrier of a clinically significant hemoglobin variant (including but not limited to Hb S, C, E mutations, beta thalassemia, alpha thalassemia or an unknown variant) within ninety days (90) days of receipt of specimen.
  6. Reports on patterns containing a hemoglobin variant(s) must state when a final determination will be completed, not to exceed ninety (90) days from receipt of specimen. Interim or incomplete information on the variant(s) will be reported if known in writing within thirty (30) days of receipt of specimen.
  7. The Vendor shall also provide consultation upon request to the newborn's physician, Sickle Cell Trait Counselor and Newborn Screening Branch staff regarding

**Exhibit A**  
Scope of Work

interpretations of laboratory data, family history or other information necessary to provide accurate diagnosis or reproductive risk counseling to families referred as a result of the California Newborn Screening Program.

8. Recommend additional appropriate laboratory tests necessary for accurate counseling or diagnosis.
  9. Test hemoglobin confirmatory specimens using the tests including DNA analyses which, after consultation with newborn's physician or consulting hematologist are determined necessary for accurate counseling.
- D. Vendor shall perform such laboratory services according to the vendor agreement at the location named on the Vendor's current State of California clinical license, unless the CDPH approves a subcontract for a portion of the testing. Consultation to providers or testing for hemoglobin specimens other than those specifically authorized by the CDPH is not covered or reimbursed by this vendor agreement.
- E. Vendor shall conduct analyses following methods approved by the Genetic Disease Laboratory Branch (GDLB). Each method shall contain a quality control program including, but not limited to the following elements:
1. Identification of calibrators and quality control reference samples by matrix and content.
  2. Placement of calibrators and quality control reference samples in each analytical run.
  3. Directions for use of calibrators in assignment of patient sample results.
  4. Instructions for interpretation of quality control results with reference samples and definition of parameters for acceptable analytical runs.
  5. Procedure for review of quality control results by the person responsible for releasing results.
  6. Definition of actions for unacceptable analytical runs, including not reporting results until those results are obtained in an analytical run that is within quality control parameters.
  7. Method for recording quality control results.

The Vendor agrees to make changes in the methods which CDPH judges to be in the best interests of the statewide newborn screening program; such changes may include items such as the amount of blood collected for testing, additional quality control actions and standardization of methods.

**Exhibit A**  
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- F. The Vendor shall provide all staff, equipment items, reagents, and consumables necessary for tests covered by the vendor agreement.
- G. The Vendor shall report inadequate specimens by telephone to the ASC, Newborn Screening Sickle Cell Trait Counselor, newborn's physician or CCS-approved Sickle Cell Disease Center requesting the test on the day of receipt within normal working hours so that an adequate repeat specimen can be obtained.
- H. If a specimen is mislabeled, inaccurately tested, damaged or lost, the Vendor must notify the ASC or Newborn Screening Sickle Cell Trait Counselor at the GDSP immediately by telephone so that an adequate repeat specimen can be obtained.
- I. The Vendor shall store specimens that remain after testing for at least thirty (30) days in a manner that preserves the integrity of the specimen. Any hemoglobin specimens transported to CDPH at CDPH request shall be transported at CDPH expense.
- J. All specimens sent for confirmatory testing for hemoglobinopathies identified in the California Newborn Screening Program, or for testing of family members of infants identified with a hemoglobin trait in the newborn screening program are the property of the State of California. The specimens cannot be used for additional testing beyond the scope of this vendor agreement for hemoglobin diagnosis without prior written permission from the GDSP.
- K. The Vendor shall subscribe to available proficiency testing programs applicable to hemoglobin test methods and shall send copies of performance reports to CDPH GDLB immediately following the receipt by the Vendor.
- L. The Vendor shall retain all laboratory records for a minimum of three (3) years following the end of the vendor agreement and make them available to CDPH staff or agents upon request.
- M. The Vendor shall provide quarterly summary reports to CDPH GDSP in a manner designated by GDSP.
- N. The Vendor shall have on site as a member of the staff of the Reference Laboratory a California licensed physician with expertise in the diagnosis of hemoglobinopathies. This expertise is demonstrated by specialty boards in hematology and by publications on the subject within the last five (5) years in accepted medical literature with peer review. Additionally, she/he shall have agreed in writing to perform all interpretations and recommendations for the Reference Laboratory and be available on site on a daily basis during normal business hours to initiate consultation on appropriate testing or counseling. The person who shall provide these services is designated as Consulting Hematologist.
- O. The Vendor shall be subject to on site inspections by CDPH GDLB and NBSB. The Vendor shall be subject to continuous contact and consultation by CDPH including review of data and records, and modification of items in the Vendor's methods,

**Exhibit A**  
Scope of Work

procedures and any other Reference Laboratory function.

- P. The Vendor shall not release, publish, put on a website, or otherwise distribute without prior written authorization from the CDPH GDSP vendor agreement liaison information acquired as a result of this work, including data, records, and information pertinent to the California Newborn Screening Program, the ASCs, the Hemoglobin Reference Laboratory or CCS-approved Sickle Cell Disease Centers.

**6. Reimbursement**

The GDSP shall reimburse the Vendor using a unit-cost methodology for services listed in Exhibit B – Vendor Payment Provision. See Exhibit B for a detailed outline of the rate schedule. The Vendor may submit itemized invoices to the GDSP for reimbursement on a quarterly basis.

Children's Hospital & Research Center Oakland  
Hemoglobin Reference Laboratory

NBS Follow-up Testing; Specimens Received 00/00/00 - 00/00/00

**Table 1**  
**Number of Individuals Tested by Reason for Test**

<b>Test Category</b>	<b>Person Tested</b>	<b># of Specimens Tested This Quarter</b>
<b>Disease Confirmation</b> (Includes transfused babies with hb pattern containing S,C,D,E or V)	Newborn	
	Mother	
	Father	
	<b>TOTAL</b>	<b>0</b>
<b>S,C,D Trait Follow-up</b>	Mother	
	Father	
	Sibling	
	<b>TOTAL</b>	<b>0</b>
<b>Other Follow-up</b> (Transfused FA, AF, or A only; patterns with 4 or more Hbs)	Newborn	
	Mother	
	Father	
	<b>TOTAL</b>	<b>0</b>
<b>TOTAL TESTED</b>	Newborn	0
	Mother	0
	Father	0
	Sibling	0
	<b>GRAND TOTAL</b>	<b>0</b>

Children's Hospital & Research Center Oakland  
 Hemoglobin Reference Laboratory

NBS Follow-up Testing; Specimens Received 00/00/00 - 00/00/00

**Table 2**  
**Total Tests by Type of Test**

Test Type	# Specimens Tested
Cellulose Acetate Electrophoresis (with Densitometry)	
Citrate Agar Electrophoresis (with Densitometry)	
Free erythrocyte protoporphyrin	
Hemogram	
High Pressure Liquid Chromatography (Hb A2, F, other)	
Isoelectric Focusing - IEF	
Solubility Test	
<b>DNA</b>	
DNA - Beta globin linear array (48 mutation panel)	
DNA - Alpha globin multiplex PCR	
DNA - direct sequencing beta globin gene	
DNA - direct sequencing alpha globin genes	
MLPA (Multiplex Ligation-dependent Probe Amplification)	
<b>Other testing - specify type</b>	
BCB (brilliant cresyl blue)	
<b>TOTAL</b>	<b>0</b>

Children's Hospital & Research Center Oakland Hemoglobin Reference Laboratory

NBS Follow-up Testing; Specimens Received 00/00/00 - 00/00/00

**Table 3: Confirmatory Results for Newborns with NBS Hb Disease Result**

<b>Final Hb Type Interpretation</b>	<b>Number</b>
Alpha Thalassemia Major	
Alpha thalassemia Trait (2-alpha globin gene deletion)	
Beta Thalassemia Major (beta0/beta0 or beta0/beta+)	
Hb C Disease (homozygous C)	
Hb C/Beta0 thalassemia	
Hb C/Beta+ thalassemia	
Hb C trait (AC)	
Hb D Disease (homozygous D)	
Hb D/beta0 thalassemia	
Hb D/beta+ thalassemia	
Hb D trait (AD)	
Hb E (homozygous E)	
Hb E/beta0 thalassemia	
Hb E/beta+ thalassemia	
Hb E/Delta beta thalassemia	
Hb E trait (AE)	
Hb H Disease	
Hb H Disease + E trait	
Hb H Constant Spring	
Hb H Variant (other alpha globin mutation)	
Hb S (homozygous S)	
Hb S/beta0 thalassemia	
Hb S/beta+ thalassemia	
Hb SC	
Hb SD	
Hb SE	
Hb S/HPFH	
Hb S/Variant	
Hb S trait (AS)	
Hb Variant/beta0 thalassemia	
Hb Variant/beta+ thalassemia	
Hb Variant/Variant	
Hb Variant trait (AV)	
HPFH (homozygous)	
Usual Hb (FA, AF or A; no disease or trait)	
Other:	
DNA pending	
<b>TOTAL</b>	<b>0</b>

**Exhibit A - Attachment I**  
Children's Hospital & Research Center Oakland  
Hemoglobin Reference Laboratory

NBS Follow-up Testing; Specimens Received 00/00/00 - 00/00/00

**Table 4**  
**Confirmatory Results Inconsistent With Newborn Screening HPLC**

Name	Accession #	Lab #	NBS Result	Confirmatory Result

**Table 5**  
**List of Newborn Screening Accession Numbers for Secimens Received this**

Attach a list of all the A#s associated with specimens received this quarter. For hemoglobin trait follow-up parent testing, use the baby's A#. Please sort the list from earliest to latest Accession number. Only one A# per family is needed.

**Exhibit B**  
**Budget Detail & Payment Provision**

**1. Invoicing and Payment**

- A. For services satisfactorily rendered, and upon receipt and approval of the invoices, the State agrees to compensate the Vendor for rates and/or allowable costs specified therein.
- B. Quarterly invoices shall include the Agreement Number and shall be submitted in triplicate in arrears. Each invoice, for the quarter, shall be submitted for payment no more than sixty (60) calendar days following the close of each quarter, and Invoices shall be submitted by the following dates:

Quarter	Invoice Submission Date
#1 - July 1 – September 30	November 1
#2 - October 1 – December 31	February 1
#3 - January 1 – March 31	May 1
#4 - April 1– June 30	August 1

Submit invoice to:

Muslimah Jaavaid, Contract Manager  
[mjaavaid@cdph.ca.gov](mailto:mjaavaid@cdph.ca.gov)  
Department of Public Health  
Genetic Disease Screening Program  
Newborn Screening Branch  
850 Marina Bay Parkway, F-175, Mail Stop 8200  
Richmond, CA 94804

C. Invoices shall:

- 1) Be prepared on company 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 actual expenses for the service performed under this contract.
- 2) Bear the Vendor's name as shown on the agreement.
- 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.
- 5) See **Exhibit B, Attachment II, Sample Invoice**.

**Exhibit B**  
**Budget Detail & Payment Provision**

D. Rates Payable

The amounts payable during this contract term for the Hemoglobin Reference Laboratory are based on the budget detail and payment provision. Reimbursement shall be made for the cost of lab tests performed. In addition, administrative costs such as equipment, equipment maintenance fees, reagents, supplies, training and information technology assistance fees up to the annual total of \$100,000 may be invoiced quarterly at  $\frac{1}{4}$  of the annual amount.

The Vendor will be reimbursed for services satisfactorily performed based on the amount payable for the contract year according to the rates list on **Exhibit B, Attachment I, Vendor Payment Provisions**.

**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 Vendor or to furnish any other considerations under this Agreement and Vendor 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 occurring to the State, or offer an agreement amendment to Vendor 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 sixty (60) 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

**Exhibit B**  
**Budget Detail & Payment Provision**

Invoice," thus indicating that all payment obligations of the State under this contract have ceased and that no further payments are due or outstanding.

- B. The State may, at its discretion, choose not to honor any delinquent final invoice if the Vendor fails to obtain prior written State approval of an alternate final invoice deadline. Written State approval shall be sought from the program contract manager prior to the expiration or termination date of this agreement.
- C. The Vendor is hereby advised of its obligation to submit, with the final invoice, a "**Contractor's Release (Exhibit G)**" acknowledging submission of the final invoice to the State and certifying the approximate percentage amount, if any, of recycled products used in performance of this contract.

**5. Fiscal Documentation**

- A. Invoices, received from a Vendor and accepted and/or submitted for payment by the State, shall not be deemed evidence of allowable agreement costs.
- B. Vendor shall maintain for review and audit and supply to CDPH upon request, adequate documentation of all payment data claimed pursuant to this agreement.
- C. If the allowability or appropriateness 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, payment may be withheld or disallowed by the State. Upon receipt of adequate documentation supporting a disallowed or questionable expense, reimbursement may resume for the amount substantiated and deemed appropriately documented.

**EXHIBIT B - ATTACHMENT I  
 VENDOR PAYMENT PROVISIONS**

**HEMOGLOBIN REFERENCE LABORATORY**

Vendor will invoice the Genetic Disease Screening program quarterly in arrears for services provided in accordance with the following schedule:

**Tests Performed**

BCB (brilliant cresyl blue)	\$135	each
Cellulose Acetate Electrophoresis (with Densitometry)	\$150	each
Citrate Agar Electrophoresis (with Densitometry)	\$150	each
Free erythrocyte protoporphyrin	\$89	each
Hemogram	\$5	each
High Pressure Liquid Chromatography (Hb A2, F, other)	\$108	each
Isoelectric Focusing - IEF	\$147	each
Solubility Test	\$111	each
DNA - Beta globin linear array (48 mutation panel)	\$250	each
DNA - Alpha globin multiplex PCR	\$250	each
DNA - direct sequencing beta globin gene	\$300	each
DNA - direct sequencing alpha globin genes	\$300	each
MLPA (Multiplex Ligation-dependent Probe Amplification)	\$300	each
Other test (specify name and cost)		each

**ADMINISTRATION**

Administration Fees (equipment, lab equipment maintenance fees, reagents, supplies, postage, training, telephone, information technology assistance, rent)	\$25,000	per quarter
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**EXHIBIT B - ATTACHMENT II  
(SAMPLE INVOICE)**

**USE YOUR OFFICIAL COMPANY LETTERHEAD**

Date: (Must be after last day of billing period)

Muslimah Jaavaid  
California Department of Public Health  
Genetic Disease Screening Program  
850 Marina Bay Parkway, Room F-175, Mail Stop 8200  
Richmond, CA 94804

Contract Number: 11-HM002  
Invoice Number: XX (Number invoices beginning with 01)  
Billing Period: (Use inclusive dates: July 1, 2011 to September 30, 2011)  
Project Title: (Example: Hemoglobin Reference Laboratory)  
(Newborn Screening Branch)

<b>Test Type</b>	<b>Cost</b>	<b># of tests this Qtr</b>	<b>Total Cost this Qtr.</b>
Cellulose Acetate Electrophoresis (with Densitometry)	\$150	88	\$13,200
Citrate Agar Electrophoresis (with Densitometry)	\$150	82	\$12,300
Free erythrocyte protoporphyrin	\$89	43	\$3,827
Hemogram	\$5	165	\$825
High Pressure Liquid Chromatography (Hb A2, F, other)	\$108	39	\$4,212
Isoelectric Focusing - IEF	\$147	205	\$30,135
Solubility Test	\$111	44	\$4,884
<b>DNA</b>			
DNA - Beta globin linear array (48 mutation panel)	\$250	104	\$26,000
DNA - Alpha globin multiplex PCR	\$250	14	\$3,500
DNA - direct sequencing beta globin gene	\$300	2	\$600
DNA - direct sequencing alpha globin genes	\$300	1	\$300
MLPA (Multiplex Ligation-dependent Probe Amplification)	\$300	0	\$0
<b>Other testing - specify type &amp; unit cost</b>			
BCB (brilliant cresyl blue)	\$135	0	\$0
<b>Quarterly Testing Total</b>			<b>\$99,783</b>
<b>Quarterly Administration Fees</b> (equipment, reagents, supplies, postage, other costs)			<b>\$25,000</b>
<b>TOTAL INVOICED AMOUNT</b>			<b>\$124,783</b>

\_\_\_\_\_  
Date

\_\_\_\_\_  
(Name and Title of above signature)

## Special Terms and Conditions

*(For State funded subvention, local assistance and direct service contracts and grant agreements)*

The use of headings or titles throughout this exhibit is for convenience only and shall not be used to interpret or govern the meaning of any specific term or condition.

The terms "contract", "Contractor" and "Subcontractor" shall also mean, "agreement", "grant", "grant agreement", "Grantee" and "Subgrantee" respectively.

The terms "California Department of Public Health" and "CDPH" shall have the same meaning and refer to the California State agency that is a party to this Agreement.

This exhibit contains provisions that require strict adherence to various contracting laws and policies. Some provisions herein are conditional and only apply if specified conditions exist (i.e., agreement total exceeds a certain amount, a specified condition applies, etc.). The provisions herein apply to this Agreement unless the provisions are removed by reference on the face of the Agreement, the provisions are superseded by an alternate provision appearing elsewhere in the Agreement, or the applicable conditions do not exist.

### Index of Special Terms and Conditions

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## 1. Travel and Per Diem Reimbursement

(Applicable if travel and/or per diem expenses are reimbursed with contract funds.)

Reimbursement for travel and per diem expenses from the California Department of Public Health (CDPH) under this Agreement shall, unless otherwise specified in this Agreement, be at the rates currently in effect, as established by the California Department of Personnel Administration (DPA), for nonrepresented state employees as stipulated in CDPH's Travel Reimbursement Information Exhibit. If the DPA rates change during the term of the Agreement, the new rates shall apply upon their effective date and no amendment to this Agreement shall be necessary. Exceptions to DPA rates may be approved by CDPH upon the submission of a statement by the Contractor indicating that such rates are not available to the Contractor. No travel outside the State of California shall be reimbursed without prior authorization from CDPH. Verbal authorization should be confirmed in writing. Written authorization may be in a form including fax or email confirmation.

## 2. Procurement Rules

(Applicable to all agreements in which equipment, property, commodities and/or supplies are furnished by CDPH or expenses for said items are reimbursed with state funds.)

### a. Equipment definitions

Wherever the term equipment and/or property is used, the following definitions shall apply:

- (1) **Major equipment:** A tangible or intangible item having a base unit cost of \$5,000 or more with a life expectancy of one (1) year or more and is either furnished by CDPH or the cost is reimbursed through this Agreement. Software and videos are examples of intangible items that meet this definition.
- (2) **Minor equipment/property:** A tangible item having a base unit cost of less than \$5,000 with a life expectancy of one (1) year or more and is either furnished by CDPH or the cost is reimbursed through this Agreement.

- b. **Government and public entities** (including state colleges/universities and auxiliary organizations), whether acting as a contractor and/or subcontractor, may secure all commodities, supplies, equipment and services related to such purchases that are required in performance of this Agreement. Said procurements are subject to Paragraphs d through h of Provision 2. Paragraph c of Provision 2 shall also apply, if equipment purchases are delegated to subcontractors that are nonprofit organizations or commercial businesses.

- c. **Nonprofit organizations and commercial businesses**, whether acting as a contractor and/or subcontractor, may secure commodities, supplies, equipment and services related to such purchases for performance under this Agreement.

- (1) Equipment purchases shall not exceed \$50,000 annually.

To secure equipment above the annual maximum limit of \$50,000, the Contractor shall make arrangements through the appropriate CDPH Program Contract Manager, to have all remaining equipment purchased through CDPH's Purchasing Unit. The cost of equipment purchased by or through CDPH shall be deducted from the funds available in this Agreement. Contractor shall submit to the CDPH Program Contract Manager a list of equipment specifications for those items that the State must procure. The State may pay the vendor directly for such arranged equipment purchases and title to the equipment will remain with CDPH. The equipment will be delivered to the Contractor's address, as stated on the face of the Agreement, unless the Contractor notifies the CDPH Program Contract Manager, in writing, of an alternate delivery address.

- (2) All equipment purchases are subject to Paragraphs d through h of Provision 2. Paragraph b of Provision 2 shall also apply, if equipment purchases are delegated to subcontractors that are either a government or public entity.

- (3) Nonprofit organizations and commercial businesses, shall use a procurement system that meets the following standards:
- (a) Maintain a code or standard of conduct that shall govern the performance of its officers, employees, or agents engaged in awarding procurement contracts. No employee, officer, or agent shall participate in the selection, award, or administration of a procurement contract in which, to his or her knowledge, he or she has a financial interest.
  - (b) Procurements shall be conducted in a manner that provides, to the maximum extent practical, open, and free competition.
  - (c) Procurements shall be conducted in a manner that provides for all of the following:
    - [1] Avoid purchasing unnecessary or duplicate items.
    - [2] Equipment solicitations shall be based upon a clear and accurate description of the technical requirements of the goods to be procured.
    - [3] Take positive steps to utilize small and veteran owned businesses.
  - d. Unless waived or otherwise stipulated in writing by CDPH, prior written authorization from the appropriate CDPH Program Contract Manager will be required before the Contractor will be reimbursed for any purchase of \$5,000 or more for commodities, supplies, equipment, and services related to such purchases. The Contractor must provide in its request for authorization all particulars necessary, as specified by CDPH, for evaluating the necessity or desirability of incurring such costs. The term "purchase" excludes the purchase of services from a subcontractor and public utility services at rates established for uniform applicability to the general public.
  - e. In special circumstances, determined by CDPH (e.g., when CDPH has a need to monitor certain purchases, etc.), CDPH may require prior written authorization and/or the submission of paid vendor receipts for any purchase, regardless of dollar amount. CDPH reserves the right to either deny claims for reimbursement or to request repayment for any Contractor and/or subcontractor purchase that CDPH determines to be unnecessary in carrying out performance under this Agreement.
  - f. The Contractor and/or subcontractor must maintain a copy or narrative description of the procurement system, guidelines, rules, or regulations that will be used to make purchases under this Agreement. The State reserves the right to request a copy of these documents and to inspect the purchasing practices of the Contractor and/or subcontractor at any time.
  - g. For all purchases, the Contractor and/or subcontractor must maintain copies of all paid vendor invoices, documents, bids and other information used in vendor selection, for inspection or audit. Justifications supporting the absence of bidding (i.e., sole source purchases) shall also be maintained on file by the Contractor and/or subcontractor for inspection or audit.
  - h. CDPH may, with cause (e.g., with reasonable suspicion of unnecessary purchases or use of inappropriate purchase practices, etc.), withhold, cancel, modify, or retract the delegated purchase authority granted under Paragraphs b and/or c of Provision 2 by giving the Contractor no less than 30 calendar days written notice.

### **3. Equipment Ownership / Inventory / Disposition**

(Applicable to agreements in which equipment and/or property is furnished by CDPH and/or when said items are purchased or reimbursed with state funds.)

- a. Wherever the terms equipment and/or property are used in Provision 3, the definitions in Provision 2, Paragraph a, shall apply.

Unless otherwise stipulated in this Agreement, all equipment and/or property that are purchased/reimbursed with agreement funds or furnished by CDPH under the terms of this Agreement shall be considered state equipment and the property of CDPH.

- (1) CDPH requires the reporting, tagging and annual inventorying of all equipment and/or property that is furnished by CDPH or purchased/reimbursed with funds provided through this Agreement.

Upon receipt of equipment and/or property, the Contractor shall report the receipt to the CDPH Program Contract Manager. To report the receipt of said items and to receive property tags, the Contractor shall use a form or format designated by CDPH's Asset Management Unit. If the appropriate form (i.e., Contractor Equipment Purchased with CDPH Funds) does not accompany this Agreement, Contractor shall request a copy from the CDPH Program Contract Manager.

- (2) If the Contractor enters into an agreement with a term of more than twelve months, the Contractor shall submit an annual inventory of state equipment and/or property to the CDPH Program Contract Manager using a form or format designated by CDPH's Asset Management Unit. If an inventory report form (i.e., Inventory/Disposition of CDPH-Funded Equipment) does not accompany this Agreement, Contractor shall request a copy from the CDPH Program Contract Manager. Contractor shall:

- (a) Include in the inventory report, equipment and/or property in the Contractor's possession and/or in the possession of a subcontractor (including independent consultants).
  - (b) Submit the inventory report to CDPH according to the instructions appearing on the form or issued by the CDPH Program Contract Manager.
  - (c) Contact the CDPH Program Contract Manager to learn how to remove, trade-in, sell, transfer or survey off, from the inventory report, expired equipment and/or property that is no longer wanted, usable or has passed its life expectancy. Instructions will be supplied by CDPH's Asset Management Unit.
- b. Title to state equipment and/or property shall not be affected by its incorporation or attachment to any property not owned by the State.
  - c. Unless otherwise stipulated, CDPH shall be under no obligation to pay the cost of restoration, or rehabilitation of the Contractor's and/or Subcontractor's facility which may be affected by the removal of any state equipment and/or property.
  - d. The Contractor and/or Subcontractor shall maintain and administer a sound business program for ensuring the proper use, maintenance, repair, protection, insurance and preservation of state equipment and/or property.
    - (1) In administering this provision, CDPH may require the Contractor and/or Subcontractor to repair or replace, to CDPH's satisfaction, any damaged, lost or stolen state equipment and/or property. In the event of state equipment and/or property theft, Contractor and/or Subcontractor shall immediately file a theft report with the appropriate police agency or the California Highway Patrol and Contractor shall promptly submit one copy of the theft report to the CDPH Program Contract Manager.
  - e. Unless otherwise stipulated by the program funding this Agreement, equipment and/or property purchased/reimbursed with agreement funds or furnished by CDPH under the terms of this Agreement, shall only be used for performance of this Agreement or another CDPH agreement.
  - f. Within sixty (60) calendar days prior to the termination or end of this Agreement, the Contractor shall provide a final inventory report of equipment and/or property to the CDPH Program Contract Manager and shall, at that time, query CDPH as to the requirements, including the manner and method, of returning state equipment and/or property to CDPH. Final disposition of equipment and/or property shall be at CDPH expense and according to CDPH instructions. Equipment

and/or property disposition instructions shall be issued by CDPH immediately after receipt of the final inventory report. At the termination or conclusion of this Agreement, CDPH may at its discretion, authorize the continued use of state equipment and/or property for performance of work under a different CDPH agreement.

**g. Motor Vehicles**

(Applicable only if motor vehicles are purchased/reimbursed with agreement funds or furnished by CDPH under this Agreement.)

- (1) If motor vehicles are purchased/reimbursed with agreement funds or furnished by CDPH under the terms of this Agreement, within thirty (30) calendar days prior to the termination or end of this Agreement, the Contractor and/or Subcontractor shall return such vehicles to CDPH and shall deliver all necessary documents of title or registration to enable the proper transfer of a marketable title to CDPH.
- (2) If motor vehicles are purchased/reimbursed with agreement funds or furnished by CDPH under the terms of this Agreement, the State of California shall be the legal owner of said motor vehicles and the Contractor shall be the registered owner. The Contractor and/or a subcontractor may only use said vehicles for performance and under the terms of this Agreement.
- (3) The Contractor and/or Subcontractor agree that all operators of motor vehicles, purchased/reimbursed with agreement funds or furnished by CDPH under the terms of this Agreement, shall hold a valid State of California driver's license. In the event that ten or more passengers are to be transported in any one vehicle, the operator shall also hold a State of California Class B driver's license.
- (4) If any motor vehicle is purchased/reimbursed with agreement funds or furnished by CDPH under the terms of this Agreement, the Contractor and/or Subcontractor, as applicable, shall provide, maintain, and certify that, at a minimum, the following type and amount of automobile liability insurance is in effect during the term of this Agreement or any period of contract extension during which any vehicle remains in the Contractor's and/or Subcontractor's possession:

**Automobile Liability Insurance**

- (a) The Contractor, by signing this Agreement, hereby certifies that it possesses or will obtain automobile liability insurance in the amount of \$1,000,000 per occurrence for bodily injury and property damage combined. Said insurance must be obtained and made effective upon the delivery date of any motor vehicle, purchased/reimbursed with agreement funds or furnished by CDPH under the terms of this Agreement, to the Contractor and/or Subcontractor.
- (b) The Contractor and/or Subcontractor shall, as soon as practical, furnish a copy of the certificate of insurance to the CDPH Program Contract Manager. The certificate of insurance shall identify the CDPH contract or agreement number for which the insurance applies.
- (c) The Contractor and/or Subcontractor agree that bodily injury and property damage liability insurance, as required herein, shall remain in effect at all times during the term of this Agreement or until such time as the motor vehicle is returned to CDPH.
- (d) The Contractor and/or Subcontractor agree to provide, at least thirty (30) days prior to the expiration date of said insurance coverage, a copy of a new certificate of insurance evidencing continued coverage, as indicated herein, for not less than the remainder of the term of this Agreement, the term of any extension or continuation thereof, or for a period of not less than one (1) year.
- (e) The Contractor and/or Subcontractor, if not a self-insured government and/or public

entity, must provide evidence, that any required certificates of insurance contain the following provisions:

- [1] The insurer will not cancel the insured's coverage without giving thirty (30) calendar days prior written notice to the State (California Department of Public Health).
  - [2] The State of California, its officers, agents, employees, and servants are included as additional insureds, but only with respect to work performed for the State under this Agreement and any extension or continuation of this Agreement.
  - [3] The insurance carrier shall notify the California Department of Public Health (CDPH), in writing, of the Contractor's failure to pay premiums; its cancellation of such policies; or any other substantial change, including, but not limited to, the status, coverage, or scope of the required insurance. Such notices shall contain a reference to each agreement number for which the insurance was obtained.
- (f) The Contractor and/or Subcontractor is hereby advised that copies of certificates of insurance may be subject to review and approval by the Department of General Services (DGS), Office of Risk and Insurance Management. The Contractor shall be notified by CDPH, in writing, if this provision is applicable to this Agreement. If DGS approval of the certificate of insurance is required, the Contractor agrees that no work or services shall be performed prior to obtaining said approval.
- (g) In the event the Contractor and/or Subcontractor fails to keep insurance coverage, as required herein, in effect at all times during vehicle possession, CDPH may, in addition to any other remedies it may have, terminate this Agreement upon the occurrence of such event.

#### 4. Subcontract Requirements

(Applicable to agreements under which services are to be performed by subcontractors including independent consultants.)

- a. Prior written authorization will be required before the Contractor enters into or is reimbursed for any subcontract for services costing \$5,000 or more. Except as indicated in Paragraph a(3) herein, when securing subcontracts for services exceeding \$5,000, the Contractor shall obtain at least three bids or justify a sole source award.
- (1) The Contractor must provide in its request for authorization, all information necessary for evaluating the necessity or desirability of incurring such cost.
  - (2) The State may identify the information needed to fulfill this requirement.
  - (3) Subcontracts performed by the following entities or for the service types listed below are exempt from the bidding and sole source justification requirements:
    - (a) A local governmental entity or the federal government,
    - (b) A State college or university from any State,
    - (c) A Joint Powers Authority,
    - (d) An auxiliary organization of a California State University or a California community college,
    - (e) A foundation organized to support the Board of Governors of the California Community Colleges,
    - (f) An auxiliary organization of the Student Aid Commission established under Education Code § 69522,
    - (g) Entities of any type that will provide subvention aid or direct services to the public,
    - (h) Entities and/or service types identified as exempt from advertising in State Contracting Manual 5.80. View this publication at the following Internet address:

<http://www.ols.dgs.ca.gov/Contract+Manual/Chapters4through6.htm>.

- b. CDPH reserves the right to approve or disapprove the selection of subcontractors and with advance written notice, require the substitution of subcontractors and require the Contractor to terminate subcontracts entered into in support of this Agreement.
  - (1) Upon receipt of a written notice from CDPH requiring the substitution and/or termination of a subcontract, the Contractor shall take steps to ensure the completion of any work in progress and select a replacement, if applicable, within 30 calendar days, unless a longer period is agreed to by CDPH.
- c. Actual subcontracts (i.e., written agreement between the Contractor and a subcontractor) of \$5,000 or more are subject to the prior review and written approval of CDPH. CDPH may, at its discretion, elect to waive this right. All such waivers shall be confirmed in writing by CDPH.
- d. Contractor shall maintain a copy of each subcontract entered into in support of this Agreement and shall, upon request by CDPH, make copies available for approval, inspection, or audit.
- e. CDPH assumes no responsibility for the payment of subcontractors used in the performance of the Agreement. Contractor accepts sole responsibility for the payment of subcontractors used in the performance of this Agreement.
- f. The Contractor is responsible for all performance requirements under this Agreement even though performance may be carried out through a subcontract.
- g. The Contractor shall ensure that all subcontracts for services include provision(s) requiring compliance with applicable terms and conditions specified in this Agreement.
- h. The Contractor agrees to include the following clause, relevant to record retention, in all subcontracts for services:

"(Subcontractor Name) agrees to maintain and preserve, until three years after termination of (Agreement Number) and final payment from CDPH to the Contractor, to permit CDPH or any duly authorized representative, to have access to, examine or audit any pertinent books, documents, papers and records related to this subcontract and to allow interviews of any employees who might reasonably have information related to such records."
- i. Unless otherwise stipulated in writing by CDPH, the Contractor shall be the subcontractor's sole point of contact for all matters related to performance and payment under this Agreement.
- j. Contractor shall, as applicable, advise all subcontractors of their obligations pursuant to the following numbered provisions of this Exhibit: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 17, 21, and/or other numbered provisions herein that are deemed applicable.

## 5. Income Restrictions

Unless otherwise stipulated in this Agreement, the Contractor agrees that any refunds, rebates, credits, or other amounts (including any interest thereon) accruing to or received by the Contractor under this Agreement shall be paid by the Contractor to CDPH, to the extent that they are properly allocable to costs for which the Contractor has been reimbursed by CDPH under this Agreement.

## 6. Audit and Record Retention

(Applicable to agreements over \$10,000.)

- a. The Contractor and/or Subcontractor shall maintain books, records, documents, and other evidence, accounting procedures, and practices, sufficient to properly reflect all direct and indirect costs of whatever nature claimed to have been incurred in the performance of this Agreement, including any matching costs and expenses. The foregoing constitutes "records" for the purposes of this provision.

- b. The Contractor's and/or Subcontractor's facility or office or such part thereof as may be engaged in the performance of this Agreement and his/her records shall be subject at all reasonable times to inspection, audit, and reproduction.
- c. Contractor agrees that CDPH, the Department of General Services, the Bureau of State Audits, or their designated representatives shall have the right to review and to copy any records and supporting documentation pertaining to the performance of this Agreement. Contractor agrees to allow the auditor(s) access to such records during normal business hours and to allow interviews of any employees who might reasonably have information related to such records. Further, the Contractor agrees to include a similar right of the State to audit records and interview staff in any subcontract related to performance of this Agreement. (GC 8546.7, CCR Title 2, Section 1896).
- d. The Contractor and/or Subcontractor shall preserve and make available his/her records (1) for a period of three years from the date of final payment under this Agreement, and (2) for such longer period, if any, as is required by applicable statute, by any other provision of this Agreement, or by subparagraphs (1) or (2) below.
  - (1) If this Agreement is completely or partially terminated, the records relating to the work terminated shall be preserved and made available for a period of three years from the date of any resulting final settlement.
  - (2) If any litigation, claim, negotiation, audit, or other action involving the records has been started before the expiration of the three-year period, the records shall be retained until completion of the action and resolution of all issues which arise from it, or until the end of the regular three-year period, whichever is later.
- e. The Contractor and/or Subcontractor shall comply with the above requirements and be aware of the penalties for violations of fraud and for obstruction of investigation as set forth in Public Contract Code § 10115.10, if applicable.
- f. The Contractor and/or Subcontractor may, at its discretion, following receipt of final payment under this Agreement, reduce its accounts, books and records related to this Agreement to microfilm, computer disk, CD ROM, or other data storage medium. Upon request by an authorized representative to inspect, audit or obtain copies of said records, the Contractor and/or subcontractor must supply or make available applicable devices, hardware, and/or software necessary to view, copy and/or print said records. Applicable devices may include, but are not limited to, microfilm readers and microfilm printers, etc.

## 7. Site Inspection

The State, through any authorized representatives, has the right at all reasonable times to inspect or otherwise evaluate the work performed or being performed hereunder including subcontract supported activities and the premises in which it is being performed. If any inspection or evaluation is made of the premises of the Contractor or Subcontractor, the Contractor shall provide and shall require Subcontractors to provide all reasonable facilities and assistance for the safety and convenience of the authorized representatives in the performance of their duties. All inspections and evaluations shall be performed in such a manner as will not unduly delay the work.

## 8. Intellectual Property Rights

### a. Ownership

- (1) Except where CDPH has agreed in a signed writing to accept a license, CDPH shall be and remain, without additional compensation, the sole owner of any and all rights, title and interest in all Intellectual Property, from the moment of creation, whether or not jointly conceived, that are made, conceived, derived from, or reduced to practice by Contractor or CDPH and which result directly or indirectly from this Agreement.

- (2) 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.
- (a) 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.
- (3) 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.
- (4) Contractor agrees to cooperate with CDPH in establishing or maintaining CDPH's exclusive rights in the Intellectual Property, and in assuring CDPH's sole rights against third parties with respect to the Intellectual Property. If the Contractor enters into any agreements or subcontracts with other parties in order to perform this Agreement, Contractor shall require the terms of the Agreement(s) to include all Intellectual Property provisions. Such terms must include, but are not limited to, the subcontractor assigning and agreeing to assign to CDPH all rights, title and interest in Intellectual Property made, conceived, derived from, or reduced to practice by the subcontractor, Contractor or CDPH and which result directly or indirectly from this Agreement or any subcontract.
- (5) 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) Except for Intellectual Property made, conceived, derived from, or reduced to practice by Contractor or CDPH and which result directly or indirectly from this Agreement, Contractor shall retain title to all of its Intellectual Property to the extent such Intellectual Property is in existence prior to the effective date of this Agreement. Contractor hereby grants to CDPH, without additional compensation, a permanent, non-exclusive, royalty free, paid-up, worldwide, irrevocable, perpetual, non-terminable license to use, reproduce, manufacture, sell, offer to sell, import, export, modify, publicly and privately display/perform, distribute, and dispose Contractor's Intellectual Property with the right to sublicense through multiple layers, for any purpose whatsoever, to the extent it is incorporated in the Intellectual Property

resulting from this Agreement, unless Contractor assigns all rights, title and interest in the Intellectual Property as set forth herein.

- (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 this provision] 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., 2006, 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**

With respect to inventions made by Contractor in the performance of this Agreement, which did not result from research and development specifically included in the Agreement's scope of work, Contractor hereby grants to CDPH a license as described under Section b of this provision for devices or material incorporating, or made through the use of such inventions. If such inventions result from research and development work specifically included within the Agreement's scope of work, then Contractor agrees to assign to CDPH, without additional compensation, all its right, title and interest in and to such inventions and to assist CDPH in securing United States and foreign patents with respect thereto.

**e. 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 Section 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 and will secure 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 and/or control, at Contractor's expense, 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. If such remedies are not reasonably available, CDPH shall be entitled to a refund of all monies paid under this Agreement, without restriction or limitation of any other rights and remedies available at law or in equity.
- (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.

## 9. Prior Approval of Training Seminars, Workshops or Conferences

Contractor shall obtain prior CDPH approval of the location, costs, dates, agenda, instructors, instructional materials, and attendees at any reimbursable training seminar, workshop, or conference conducted pursuant to this Agreement and of any reimbursable publicity or educational materials to be made available for distribution. The Contractor shall acknowledge the support of the State whenever publicizing the work under this Agreement in any media. This provision does not apply to necessary staff meetings or training sessions held for the staff of the Contractor or Subcontractor to conduct routine business matters.

## 10. 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.
- 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.

## 11. Documents, Publications and Written Reports

(Applicable to agreements over \$5,000 under which publications, written reports and documents are developed or produced. Government Code Section 7550.)

Any document, publication or written report (excluding progress reports, financial reports and normal contract communications) prepared as a requirement of this Agreement shall contain, in a separate section preceding the main body of the document, the number and dollar amounts of all contracts and subcontracts relating to the preparation of such document or report, if the total cost for work by nonemployees of the State exceeds \$5,000.

## 12. Dispute Resolution Process

- a. 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.

(1) 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.
- (2) When appealing to the second level, the Contractor must prepare an appeal indicating the reasons for disagreement with 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.
- b. If the Contractor wishes to appeal the decision of the Deputy Director of the division in which the branch is organized or his/her designee, the Contractor shall follow the procedures set forth in Division 25.1 (commencing with Section 38050) of the Health and Safety Code and the regulations adopted thereunder. (Title 1, Subchapter 2.5, commencing with Section 251, California Code of Regulations.)
- c. Disputes arising out of an audit, examination of an agreement or other action not covered by subdivision (a) of Section 20204, of Chapter 2.1, Title 22, of the California Code of Regulations, and for which no procedures for appeal are provided in statute, regulation or the Agreement, shall be handled in accordance with the procedures identified in Sections 51016 through 51047, Title 22, California Code of Regulations.
- d. Unless otherwise stipulated in writing by CDPH, all dispute, grievance and/or appeal correspondence shall be directed to the CDPH Program Contract Manager.
- e. 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.

### 13. Financial and Compliance Audit Requirements

- a. The definitions used in this provision are contained in Section 38040 of the Health and Safety Code, which by this reference is made a part hereof.
- b. Direct service contract means a contract or agreement for services contained in local assistance or subvention programs or both (see Health and Safety [H&S] Code Section 38020). Direct service contracts shall not include contracts, agreements, grants, or subventions to other governmental agencies or units of government nor contracts or agreements with regional centers or area agencies on aging (See H&S Code Section 38030).
- c. The Contractor, as indicated below, agrees to obtain one of the following audits:
- (1) ***If the Contractor is a nonprofit organization (as defined in H&S Code Section 38040) and receives \$25,000 or more from any State agency under a direct service contract or agreement;*** the Contractor agrees to obtain an annual single, organization wide, financial and compliance audit. Said audit shall be conducted according to Generally Accepted Auditing Standards. This audit does not fulfill the audit requirements of Paragraph c(3) below. The audit shall be completed by the 15th day of the fifth month following the end of the Contractor's fiscal year, **and/or**

- (2) ***If the Contractor is a nonprofit organization (as defined in H&S Code Section 38040) and receives less than \$25,000 per year from any State agency under a direct service contract or agreement,*** the Contractor agrees to obtain a biennial single, organization wide financial and compliance audit, unless there is evidence of fraud or other violation of state law in connection with this Agreement. This audit does not fulfill the audit requirements of Paragraph c(3) below. The audit shall be completed by the 15th day of the fifth month following the end of the Contractor's fiscal year, **and/or**
- (3) ***If the Contractor is a State or Local Government entity or Nonprofit organization (as defined by the Federal Office of Management and Budget [OMB] Circular A-133) and expends \$500,000 or more in Federal awards,*** the Contractor agrees to obtain an annual single, organization wide, financial and compliance audit according to the requirements specified in OMB Circular A-133 entitled "Audits of States, Local Governments, and Non-Profit Organizations". An audit conducted pursuant to this provision will fulfill the audit requirements outlined in Paragraphs c(1) and c(2) above. The audit shall be completed by the end of the ninth month following the end of the audit period. The requirements of this provision apply if:
- (a) The Contractor is a recipient expending Federal awards received directly from Federal awarding agencies, or
  - (b) The Contractor is a subrecipient expending Federal awards received from a pass-through entity such as the State, County or community based organization.
- (4) If the Contractor submits to CDPH a report of an audit other than an OMB A-133 audit, the Contractor must also submit a certification indicating the Contractor has not expended \$500,000 or more in federal funds for the year covered by the audit report.
- d. Two copies of the audit report shall be delivered to the CDPH program funding this Agreement. The audit report must identify the Contractor's legal name and the number assigned to this Agreement. The audit report shall be due within 30 days after the completion of the audit. Upon receipt of said audit report, the CDPH Program Contract Manager shall forward the audit report to CDPH's Audits and Investigations Unit if the audit report was submitted under Section 13c(3), unless the audit report is from a City, County, or Special District within the State of California whereby the report will be retained by the funding program.
  - e. The cost of the audits described herein may be included in the funding for this Agreement up to the proportionate amount this Agreement represents of the Contractor's total revenue. The CDPH program funding this Agreement must provide advance written approval of the specific amount allowed for said audit expenses.
  - f. The State or its authorized designee, including the Bureau of State Audits, is responsible for conducting agreement performance audits which are not financial and compliance audits. Performance audits are defined by Generally Accepted Government Auditing Standards.
  - g. Nothing in this Agreement limits the State's responsibility or authority to enforce State law or regulations, procedures, or reporting requirements arising thereto.
  - h. Nothing in this Agreement limits the authority of the State to make audits of this Agreement, provided however, that if independent audits arranged for by the Contractor meet Generally Accepted Governmental Auditing Standards, the State shall rely on those audits and any additional audit work and shall build upon the work already done.
  - i. The State may, at its option, direct its own auditors to perform either of the audits described above. The Contractor will be given advance written notification, if the State chooses to exercise its option to perform said audits.

**14. Novation Requirements**

If the Contractor proposes any novation agreement, CDPH shall act upon the proposal within 60 days after receipt of the written proposal. CDPH may review and consider the proposal, consult and negotiate with the Contractor, and accept or reject all or part of the proposal. Acceptance or rejection of the proposal may be made orally within the 60-day period and confirmed in writing within five days of said decision. Upon written acceptance of the proposal, CDPH will initiate an amendment to this Agreement to formally implement the approved proposal.

**15. Payment Withholds**

(Applicable only if a final report is required by this Agreement. Not applicable to government entities.)

Unless waived or otherwise stipulated in this Agreement, CDPH may, at its discretion, withhold 10 percent (10%) of the face amount of the contract, 50 percent (50%) of the final invoice, or \$3,000 whichever is greater, until CDPH receives a final report that meets the terms, conditions and/or scope of work requirements of this Agreement.

**16. Performance Evaluation**

(Not applicable to grant agreements.)

CDPH may, at its discretion, evaluate the performance of the Contractor at the conclusion of this Agreement. If performance is evaluated, the evaluation shall not be a public record and shall remain on file with CDPH. Negative performance evaluations may be considered by CDPH prior to making future contract awards.

**17. Officials Not to Benefit**

No members of or delegate of Congress or the State Legislature shall be admitted to any share or part of this Agreement, or to any benefit that may arise therefrom. This provision shall not be construed to extend to this Agreement if made with a corporation for its general benefits.

**18. Four-Digit Date Compliance**

(Applicable to agreements in which Information Technology (IT) services are provided to CDPH or if IT equipment is procured.)

Contractor warrants that it will provide only Four-Digit Date Compliant (as defined below) Deliverables and/or services to the State. "Four Digit Date compliant" Deliverables and services can accurately process, calculate, compare, and sequence date data, including without limitation date data arising out of or relating to leap years and changes in centuries. This warranty and representation is subject to the warranty terms and conditions of this Contract and does not limit the generality of warranty obligations set forth elsewhere herein.

**19. Union Organizing**

(Applicable only to grant agreements.)

Grantee, by signing this Agreement, hereby acknowledges the applicability of Government Code Sections 16645 through 16649 to this Agreement. Furthermore, Grantee, by signing this Agreement, hereby certifies that:

- a. No state funds disbursed by this grant will be used to assist, promote or deter union organizing.
- b. Grantee shall account for state funds disbursed for a specific expenditure by this grant, to show those funds were allocated to that expenditure.

- c. Grantee shall, where state funds are not designated as described in b herein, allocate, on a pro-rata basis, all disbursements that support the grant program.
- d. If Grantee makes expenditures to assist, promote or deter union organizing, Grantee will maintain records sufficient to show that no state funds were used for those expenditures, and that Grantee shall provide those records to the Attorney General upon request.

## 20. Contract Uniformity (Fringe Benefit Allowability)

(Applicable only to nonprofit organizations.)

Pursuant to the provisions of Article 7 (commencing with Section 100525) of Chapter 3 of Part 1 of Division 101 of the Health and Safety Code, CDPH sets forth the following policies, procedures, and guidelines regarding the reimbursement of fringe benefits.

- a. As used herein fringe benefits shall mean an employment benefit given by one's employer to an employee in addition to one's regular or normal wages or salary.
- b. As used herein, fringe benefits do not include:
  - (1) Compensation for personal services paid currently or accrued by the Contractor for services of employees rendered during the term of this Agreement, which is identified as regular or normal salaries and wages, annual leave, vacation, sick leave, holidays, jury duty and/or military leave/training.
  - (2) Director's and executive committee member's fees.
  - (3) Incentive awards and/or bonus incentive pay.
  - (4) Allowances for off-site pay.
  - (5) Location allowances.
  - (6) Hardship pay.
  - (7) Cost-of-living differentials
- c. Specific allowable fringe benefits include:
  - (1) Fringe benefits in the form of employer contributions for the employer's portion of payroll taxes (i.e., FICA, SUI, SDI), employee health plans (i.e., health, dental and vision), unemployment insurance, worker's compensation insurance, and the employer's share of pension/retirement plans, provided they are granted in accordance with established written organization policies and meet all legal and Internal Revenue Service requirements.
- d. To be an allowable fringe benefit, the cost must meet the following criteria:
  - (1) Be necessary and reasonable for the performance of the Agreement.
  - (2) Be determined in accordance with generally accepted accounting principles.
  - (3) Be consistent with policies that apply uniformly to all activities of the Contractor.
- e. Contractor agrees that all fringe benefits shall be at actual cost.
- f. Earned/Accrued Compensation
  - (1) Compensation for vacation, sick leave and holidays is limited to that amount earned/accrued within the agreement term. Unused vacation, sick leave and holidays earned from periods prior to the agreement term cannot be claimed as allowable costs. See Provision f (3)(a) for an example.
  - (2) For multiple year agreements, vacation and sick leave compensation, which is earned/accrued but not paid, due to employee(s) not taking time off may be carried over and claimed within the overall term of the multiple years of the Agreement. Holidays cannot be carried over from one agreement year to the next. See Provision f (3)(b) for an example.

- (3) For single year agreements, vacation, sick leave and holiday compensation that is earned/accrued but not paid, due to employee(s) not taking time off within the term of the Agreement, cannot be claimed as an allowable cost. See Provision f (3)(c) for an example.

(a) **Example No. 1:**

If an employee, John Doe, earns/accrues three weeks of vacation and twelve days of sick leave each year, then that is the maximum amount that may be claimed during a one year agreement. If John Doe has five weeks of vacation and eighteen days of sick leave at the beginning of the Agreement, the Contractor during a one-year agreement term may only claim up to three weeks of vacation and twelve days of sick leave actually used by the employee. Amounts earned/accrued in periods prior to the beginning of the Agreement are not an allowable cost.

(b) **Example No. 2:**

If during a three-year (multiple year) agreement, John Doe does not use his three weeks of vacation in year one, or his three weeks in year two, but he does actually use nine weeks in year three; the Contractor would be allowed to claim all nine weeks paid for in year three. The total compensation over the three-year period cannot exceed 156 weeks (3 x 52 weeks).

(c) **Example No. 3:**

If during a single year agreement, John Doe works fifty weeks and used one week of vacation and one week of sick leave and all fifty-two weeks have been billed to CDPH, the remaining unused two weeks of vacation and seven days of sick leave may not be claimed as an allowable cost..

## 21. Prohibited Use of State Funds for Software

(Applicable to agreements in which computer software is used in performance of the work.)

Contractor certifies that 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.

**Exhibit E**  
Additional Provisions

**1. Agreement Amendments**

Should either party, during the term of this agreement, desire a change or amendment to the terms of this Agreement, such changes or amendments shall be proposed in writing to the other party, who will respond in writing as to whether the proposed changes/amendments are accepted or rejected. If accepted and after negotiations are concluded, the agreed upon changes shall be made through the State's official agreement amendment process. No amendment will be considered binding on either party until it is formally approved by the State.

**2. Cancellation / Termination**

- 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 for cause. 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 termination or cancellation 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 termination or cancellation, the Contractor shall take immediate steps to stop performance and to cancel or reduce subsequent agreement costs.
- F. In the event of early termination or cancellation, 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.

**3. Dispute Resolution Process**

If the Vendor believes there is a dispute or grievance between Vendor and CDPH, both parties shall follow the two-step procedure outlined below.

- A. The Vendor should first discuss the problem informally with the NBSB Area Service Center Liaison. If the problem cannot be resolved at this stage, the Vendor must direct the grievance together with any evidence, in writing, to the program Branch Chief. The grievance must state the issues in dispute, the legal authority or other basis for the Vendor's position and the remedy sought. The

**Exhibit E**  
Additional Provisions

Branch Chief must make a determination on the problem within ten (10) working days after receipt of the written communication from the Vendor. The Branch Chief shall respond in writing to the Vendor indicating the decision and reasons therefore. Should the Vendor disagree with the Branch Chief's decision, the Vendor may appeal to the second level.

- B. The Vendor must prepare a letter indicating why the Branch Chief's decision is unacceptable, attaching to it the Vendor's original statement of the dispute with supporting documents along with a copy of the Branch Chief's response. This letter shall be sent to the Deputy Director of the division in which the section is organized within ten (10) working days from receipt of the Branch Chief's decision. The Deputy Director or designee shall meet with the Vendor to review the issues raised. A written decision signed by the Deputy Director or designee shall be returned to the Vendor within twenty (20) working days of receipt of the Vendor's letter.

**4. Loss Leader**

It is unlawful for any person engaged in business within this State to sell or use any article or product as a "loss leader" as defined in Section 17030 of the Business and Professions Code. A "loss leader" is any article or product sold at less than cost (a) where the purpose is to induct, promote or encourage the purchase of other merchandise; or (b) Where the effect is a tendency or capacity to mislead or deceive purchasers or prospective purchasers; or (c) where the effect is to divert trade from or otherwise injure competitors.

**5. Confidentiality of Information**

- A. The vendor and its employees or agents shall comply with the provisions of the California Confidentiality of Medical Information Act, Civil Code Sections 56 et seq., the Hereditary Disorders Act, Health and Safety Code Sections 124975 et seq., HIPAA and its implementing privacy and security @ 45 CFR parts 160 and 164 (the HIPAA regulation).

**6. Avoidance of Conflicts of Interest by Vendor**

- A. CDPH intends to avoid any real or apparent conflict of interest on the part of the Vendor or employees, officers and directors of the Vendor. Thus, CDPH reserves the right to determine, at its sole discretion, whether any information, assertion or claim received from any source indicates the existence of a real or apparent conflict of interest under this agreement; and if a conflict is found to exist, to require the Vendor to submit additional information or a plan for resolving the conflict, subject to CDPH review and prior approval.

**Exhibit E**  
Additional Provisions

B. Conflicts of interest include, but are not limited to:

- 1) An instance where the Vendor or any employee, officer, or director of the Vendor has an interest, financial or otherwise, whereby the use or disclosure of information obtained while performing services under this agreement would allow for private or personal benefit or for any purpose that is contrary to the goals and objectives of this agreement.
- 2) An instance where the Vendor's employees, officers, or directors use their positions for purposes that are, or give the appearance of being, motivated by a desire for private gain for themselves or others, such as those with whom they have family, business or other ties.

C. If CDPH is or becomes aware of a known or suspected conflict of interest, the Vendor will be given an opportunity to submit additional information or to resolve the conflict. A Vendor with a suspected conflict of interest under this agreement will have five (5) working days from the date of notification of the conflict by CDPH to provide complete information regarding the suspected conflict. If a conflict of interest under this agreement is determined to exist by CDPH and cannot be resolved to the satisfaction of CDPH, the conflict will be grounds for terminating this agreement. CDPH may, at its discretion upon receipt of a written request from the Vendor, authorize an extension of the timeline indicated herein.

**Exhibit F**

## HIPAA Business Associate Exhibit

**I. Recitals**

- A. This Contract (Agreement) has been determined to constitute a business associate relationship under the Health Insurance Portability and Accountability Act ("HIPAA") and its implementing privacy and security regulations at 45 CFR Parts 160 and 164 ("the HIPAA regulations:").
- B. The California Department of Public Health ("CDPH") wishes to disclose to Business Associate certain information pursuant to the terms of this Agreement, some of which may constitute Protected Health Information ("PHI") pursuant to HIPAA regulations.
- C. "Protected Health Information" or "PHI" means any information, whether oral or recorded in any form or medium that relates to the past, present, or future physical or mental condition of an individual, the provision of health and dental care to an individual, or the past, present, or future payment for the provision of health and dental care to an individual; and that identifies the individual or with respect to which there is a reasonable basis to believe the information can be used to identify the individual. PHI shall have the meaning given to such term under HIPAA and HIPAA regulations, as the same may be amended from time to time.
- D. "Security Incident" means the attempted or successful unauthorized access, use, disclosure, modification, or destruction of PHI, or confidential data that is essential to the ongoing operation of the Business Associate's organization and intended for internal use; or interference with system operations in an information system.
- E. As set forth in this Agreement Contractor is the Business Associate of CDPH that 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.
- F. CDPH and Business Associate desire to protect the privacy and provide for the security of PHI created, received, maintained, transmitted, used or disclosed pursuant to this Agreement, in compliance with HIPAA and HIPAA regulations.
- G. The purpose of this Exhibit is to satisfy certain standards and requirements of HIPAA and the HIPAA regulations, and other applicable laws.
- H. The terms used in this Exhibit, but not otherwise defined, shall have the same meanings as those terms are defined in the HIPAA regulations.

In exchanging information pursuant to this Agreement, the parties agree as follows:

**II Permitted Uses and Disclosures of PHI by Business Associate**

- A. **Permitted Uses and Disclosures.** Except as otherwise indicated in this Exhibit, Business Associate may use or disclose PHI only to perform functions, activities or services specified in this Agreement, for, or on behalf of CDPH, provided that such use or disclosure would not violate the HIPAA regulations, if done by CDPH.
- B. **Specific Use and Disclosure Provisions.** Except as otherwise indicated in this Exhibit, Business Associate may:

**Exhibit F**

## HIPAA Business Associate Exhibit

- 1) **Use and disclose for management and administration.** Use and disclose PHI for the proper management and administration of the Business Associate or to carry out the legal responsibilities of the Business Associate, provided that disclosures are required by law, or the Business Associate 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 the Business Associate of any instances of which it is aware that the confidentiality of the information has been breached.
- 2) **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 the Business Associate on behalf of CDPH with PHI received by the Business Associate in its capacity as the Business Associate of another covered entity, to permit data analyses that relate to the health care operations of CDPH.

**II. Responsibilities of Business Associate**

Business Associate agrees:

- A. **Nondisclosure.** Not to use or disclose Protected Health Information (PHI) other than as permitted or required by this Agreement or as required by law.
- B. **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; and to prevent use or disclosure of PHI other than as provided for by this Agreement. Business Associate 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 the Business Associate's operations and the nature and scope of its activities, and which incorporates the requirements of section C, Security, below. Business Associate will provide CDPH with its current and updated policies.
- C. **Security.** The Business Associate shall take any and all steps necessary to ensure the continuous security of all computerized data systems containing CDPH PHI. These steps shall include, at a minimum:
  - 1) complying with all of the data system security precautions listed in the Business Associate Data Security Standards set forth in Attachment 1 to this Exhibit;
  - 2) 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

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 CDPH PHI from breaches and security incidents.

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

**Exhibit F**

## HIPAA Business Associate Exhibit

- E. **Business Associate's Agents.** To ensure that any agents, including subcontractors, to whom Business Associate provides PHI received from or created or received by Business Associate on behalf of CDPH, agree to the same restrictions and conditions that apply to Business Associate with respect to such PHI, including implementation of reasonable and appropriate administrative, physical, and technical safeguards to protect such PHI; and to incorporate, when applicable, the relevant provisions of this Exhibit into each subcontract or subaward to such agents or subcontractors.
- F. **Availability of Information to CDPH and Individuals.** To provide access as CDPH may require, and in the time and manner designated by CDPH (upon reasonable notice and during Business Associate'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 care component health plans; or those records used to make decisions about individuals on behalf of CDPH. Business Associate 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.
- 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 Business Associate's internal practices, books and records relating to the use and disclosure of PHI received from CDPH, or created or received by Business Associate on behalf of CDPH, available to CDPH or to the Secretary of the U.S. Department of Health and Human Services in a time and manner designated by CDPH or by the Secretary, for purposes of determining CDPH's compliance with the HIPAA regulations.
- 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 45 CFR 164.528.
- J. **Notification of Breach.** During the term of this Agreement:
- 1) **Discovery of Breach.** To notify CDPH **immediately by telephone call plus email or fax** upon the discovery of breach of security of PHI in computerized form if the PHI was, or is reasonably believed to have been, acquired by an unauthorized person, or **within 24 hours by email or fax** of the discovery of any suspected security incident, intrusion or unauthorized use or disclosure of PHI in violation of this Agreement and this Exhibit, or potential loss of confidential data affecting this Agreement. Notification shall be provided to the CDPH Program Contract Manager, the CDPH Privacy Officer and the CDPH Chief Information Security Officer. If the incident occurs after business hours or on a weekend or holiday and involves electronic PHI, notification shall be provided by calling the CDPH ITSD Help Desk. Business Associate shall take:
    - i. Prompt corrective action to mitigate any risks or damages involved with the breach and to protect the operating environment and
    - ii. Any action pertaining to such unauthorized disclosure required by applicable Federal and State laws and regulations.

**Exhibit F**

HIPAA Business Associate Exhibit

- 2) **Investigation of Breach.** To immediately investigate such security incident, breach, or unauthorized use or disclosure of PHI or confidential data. **Within 72 hours of the discovery**, to notify the CDPH Program Contract Manager(s), the CDPH Privacy Officer, and the CDPH Chief Information Security Officer of:
  - i. What data elements were involved and the extent of the data involved in the breach,
  - ii. A description of the unauthorized persons known or reasonably believed to have improperly used or disclosed PHI or confidential data,
  - iii. A description of where the PHI or confidential data is believed to have been improperly transmitted, sent, or utilized,
  - iv. A description of the probable causes of the improper use or disclosure; and
  - v. Whether Civil Code sections 1798.29 or 1798.82 or any other federal or state laws requiring individual notifications of breaches are triggered.
  
- 3) **Written Report.** To provide a written report of the investigation to the CDPH Program Contract Managers, the CDPH Privacy Officer, and the CDPH Chief Information Security Officer within ten (10) working days of the discovery of the breach or unauthorized use or disclosure. The report shall include, but not be limited to, the information specified above, as well as a full, detailed corrective action plan, including information on measures that were taken to halt and/or contain the improper use or disclosure.
  
- 4) **Notification of Individuals.** To notify individuals of the breach or unauthorized use or disclosure when notification is required under state or federal law and to pay any costs of such notifications, as well as any costs associated with the breach. The CDPH Program Contract Managers, the CDPH Privacy Officer, and the CDPH Chief Information Security Officer shall approve the time, manner and content of any such notifications.
  
- 5) **CDPH Contact Information.** To direct communications to the above referenced CDPH staff, the Contractor shall initiate contact as indicated herein. CDPH reserves the right to make changes to the contact information below by giving written notice to the Contractor. Said changes shall not require an amendment to this Exhibit or the Agreement to which it is incorporated.

<b>CDPH Program Contract Manager</b>	<b>CDPH Privacy Officer</b>	<b>CDPH Chief Information Security Officer</b>
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 P.O. Box 997377, MS 0505 Sacramento, CA 95899-7377  Email: <a href="mailto:privacy@cdph.ca.gov">privacy@cdph.ca.gov</a> Telephone: (916) 440-7671	Chief Information Security Officer Information Security Office California Department of Public Health P.O. Box 997413, MS 6302 Sacramento, CA 95899-7413  Email: <a href="mailto:cdphiso@cdph.ca.gov">cdphiso@cdph.ca.gov</a> Telephone: IT Service Desk (916) 440-7000 or (800) 579-0874

**Exhibit F**

## HIPAA Business Associate Exhibit

K. **Employee Training and Discipline.** To train and use reasonable measures to ensure compliance with the requirements of this Exhibit by employees who assist in the performance of functions or activities on behalf of CDPH under this Agreement and use or disclose PHI; and discipline such employees who intentionally violate any provisions of this Exhibit, including by termination of employment. In complying with the provisions of this section K, Business Associate shall observe the following requirements:

- 1) Business Associate shall provide information privacy and security training, at least annually, at its own expense, to all its employees who assist in the performance of functions or activities on behalf of CDPH under this Agreement and use or disclose PHI.
- 2) Business Associate shall require each employee who receives information privacy and security training to sign a certification, indicating the employee's name and the date on which the training was completed.
- 3) Business Associate shall retain each employee's written certifications for CDPH inspection for a period of three years following contract termination.

**III. Obligations of CDPH**

CDPH agrees to:

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

**IV. Audits, Inspection and Enforcement**

From time to time, CDPH may inspect the facilities, systems, books and records of Business Associate to monitor compliance with this Agreement and this Exhibit. Business Associate shall promptly remedy any violation of any provision of this Exhibit and shall certify the same to the CDPH Privacy Officer or the CDPH Chief Information Security 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 Exhibit, nor does CDPH's:

**Exhibit F**

## HIPAA Business Associate Exhibit

- A. Failure to detect or
- B. 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 this Agreement and this Exhibit.

**V. Termination**

- A. **Termination for Cause.** Upon CDPH's knowledge of a material breach of this Exhibit by Business Associate, CDPH shall:
  - 1) Provide an opportunity for Business Associate to cure the breach or end the violation and terminate this Agreement if Business Associate does not cure the breach or end the violation within the time specified by CDPH;
  - 2) Immediately terminate this Agreement if Business Associate has breached a material term of this Exhibit and cure is not possible; or
  - 3) If neither cure nor termination is feasible, report the violation to the Secretary of the U.S. Department of Health and Human Services.
- B. **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 this Agreement if Business Associate is found guilty of a criminal violation of HIPAA. CDPH may terminate this Agreement if a finding or stipulation that the 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 the Business Associate is a party or has been joined.
- C. **Effect of Termination.** Upon termination or expiration of this Agreement for any reason, Business Associate shall promptly 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 or, if return or destruction is not feasible, shall continue to extend the protections of this Exhibit to such information, 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.

**VI. Miscellaneous Provisions**

- A. **Disclaimer.** CDPH makes no warranty or representation that compliance by Business Associate with this Exhibit, 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.

**Exhibit F**

## HIPAA Business Associate Exhibit

- 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 Exhibit 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 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 amendment to this Exhibit embodying written assurances consistent with the standards and requirements of HIPAA, the HIPAA regulations or other applicable laws. CDPH may terminate this Agreement upon thirty (30) days written notice in the event:
- 1) Business Associate does not promptly enter into negotiations to amend this Exhibit when requested by CDPH pursuant to this Section or
  - 2) Business Associate does not enter into an amendment providing assurances regarding the safeguarding and security 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 this 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 the 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 Exhibit 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 Exhibit shall be interpreted as broadly as necessary to implement and comply with HIPAA, the HIPAA regulations and applicable state laws. The parties agree that any ambiguity in the terms and conditions of this Exhibit shall be resolved in favor of a meaning that complies and is consistent with HIPAA and the HIPAA regulations.
- F. **Regulatory References.** A reference in the terms and conditions of this Exhibit 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.C of this Exhibit shall survive the termination or expiration of this 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 F**

## HIPAA Business Associate Exhibit

**Attachment 1**

## Business Associate Data Security Standards

**1. General Security Controls**

- A. **Confidentiality Statement.** All persons that will be working with CDPH PHI must sign a confidentiality statement. The statement must include 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. The statement must be renewed annually. The Business Associate shall retain each person's written confidentiality statement for CDPH inspection for a period of three (3) years following contract termination.
- B. **Background check.** Before a member of the Business Associate's workforce may access CDPH PHI, Business Associate must conduct a thorough background check of that worker and evaluate the results to assure that there is no indication that the worker may present a risk for theft of confidential data. The Business Associate shall retain each workforce member's background check documentation for a period of three (3) years following contract termination.
- C. **Workstation/Laptop encryption.** All workstations and laptops that process and/or store CDPH PHI must be encrypted using a FIPS 140-2 certified algorithm, such as Advanced Encryption Standard (AES), with a 128bit key or higher. The encryption solution must be full disk unless approved by the CDPH Information Security Office.
- D. **Server Security.** Servers containing unencrypted CDPH PHI must have sufficient administrative, physical, and technical controls in place to protect that data, based upon a risk assessment/system security review.
- E. **Minimum Necessary.** Only the minimum necessary amount of CDPH PHI required to perform necessary business functions may be copied, downloaded, or exported.
- F. **Removable media devices.** All electronic files that contain CDPH PHI 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.). Must be encrypted using a FIPS 140-2 certified algorithm, such as Advanced Encryption Standard (AES), with a 128bit key or higher
- G. **Antivirus software.** All workstations, laptops and other systems that process and/or store CDPH PHI must install and actively use comprehensive anti-virus software solution with automatic updates scheduled at least daily.
- H. **Patch Management.** All workstations, laptops and other systems that process and/or store CDPH PHI must have security patches applied, with system reboot if necessary. There must be a documented patch management process which determines installation

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## HIPAA Business Associate Exhibit

timeframe based on risk assessment and vendor recommendations. At a maximum, all applicable patches must be installed within 30 days of vendor release.

- I. **User IDs and Password Controls.** All users must be issued a unique user name for accessing CDPH PHI. Username must be promptly disabled, deleted, or the password changed upon the transfer or termination of an employee with knowledge of the password. Passwords are not to be shared. Must be at least eight characters. Must be a non-dictionary word. Must not be stored in readable format on the computer. Must be changed every 60 days. Must be changed if revealed or compromised. 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)
- J. **Data Sanitization.** All CDPH PHI must be sanitized using NIST Special Publication 800-88 standard methods for data sanitization when the CDPH PSCI is no longer needed.

**2. System Security Controls**

- A. **System Timeout.** The system must provide an automatic timeout, requiring re-authentication of the user session after no more than 20 minutes of inactivity.
- B. **Warning Banners.** All systems containing CDPH PHI must display a warning banner stating that data is confidential, systems are logged, and system use is for business purposes only. User must be directed to log off the system if they do not agree with these requirements.
- C. **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 which alters CDPH PHI. 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 is stored in a database, database logging functionality must be enabled. Audit trail data must be archived for at least 3 years after occurrence.
- D. **Access Controls.** The system must use role based access controls for all user authentications, enforcing the principle of least privilege.
- E. **Transmission encryption.** All data transmissions of CDPH PHI outside the secure internal network must be encrypted using a FIPS 140-2 certified algorithm, such as Advanced Encryption Standard (AES), with a 128bit key or higher. Encryption can be end to end at the network level, or the data files containing CDPH PHI can be encrypted. This requirement pertains to any type of CDPH PHI in motion such as website access, file transfer, and E-Mail.

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- F. **Intrusion Detection.** All systems involved in accessing, holding, transporting, and protecting CDPH PHI that are accessible via the Internet must be protected by a comprehensive intrusion detection and prevention solution.

**3. Audit Controls**

- A. **System Security Review.** All systems processing and/or storing CDPH PHI 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 shall include vulnerability scanning tools.
- B. **Log Reviews.** All systems processing and/or storing CDPH PHI 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 must have a documented change control procedure that ensures separation of duties and protects the confidentiality, integrity and availability of data.

**4. Business Continuity / Disaster Recovery Controls**

- a. **Disaster Recovery.** Business Associate must establish a documented plan to enable continuation of critical business processes and protection of the security of electronic CDPH PHI 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 this agreement for more than 24 hours.

**Data Backup Plan.** Business Associate must have established documented procedures to backup CDPH PHI to maintain retrievable exact copies of CDPH PHI. The plan must include a regular schedule for making backups, storing backups offsite, an inventory of backup media, and the amount of time to restore CDPH PHI should it be lost. At a minimum, the schedule must be a weekly full backup and monthly offsite storage of CDPH data.

**5. Paper Document Controls**

- A. **Supervision of Data.** CDPH PHI 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 an employee authorized to access the information. CDPH PHI 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 is contained shall be escorted and CDPH Protected Health Information shall be kept out of sight while visitors are in the area.

**Exhibit F**

HIPAA Business Associate Exhibit

- C. **Confidential Destruction.** CDPH PHI must be disposed of through confidential means, using NIST Special Publication 800-88 standard methods for data sanitization when the CDPH PSCI is no longer needed.
- D. **Removal of Data.** CDPH PHI must not be removed from the premises of the Business Associate except with express written permission of CDPH.
- E. **Faxing.** Faxes containing CDPH PHI 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.
- F. **Mailing.** CDPH PHI shall only be mailed using secure methods. Large volume mailings of CDPH Protected Health Information shall be by a secure, bonded courier with signature required on receipt. Disks and other transportable media sent through the mail must be encrypted with a CDPH approved solution, such as a solution using a vendor product specified on the CSSI.

## Contractor's Release

### Instructions to Contractor:

**With final invoice(s) submit one (1) original and one (1) copy.** The original must bear the original signature of a person authorized to bind the Contractor. The additional copy may bear photocopied signatures.

### Submission of Final Invoice

Pursuant to **contract number** 11-HM002 entered into between the State of California Department of Public Health (CDPH) and the Contractor (identified below), the Contractor does acknowledge that final payment has been requested via **invoice number(s)** \_\_\_\_\_, in the **amount(s) of \$** \_\_\_\_\_ and **dated** \_\_\_\_\_.  
If necessary, enter "See Attached" in the appropriate blocks and attach a list of invoice numbers, dollar amounts and invoice dates.

### Release of all Obligations

By signing this form, and upon receipt of the amount specified in the invoice number(s) referenced above, the Contractor does hereby release and discharge the State, its officers, agents and employees of and from any and all liabilities, obligations, claims, and demands whatsoever arising from the above referenced contract.

### Repayments Due to Audit Exceptions / Record Retention

By signing this form, Contractor acknowledges that expenses authorized for reimbursement does not guarantee final allowability of said expenses. Contractor agrees that the amount of any sustained audit exceptions resulting from any subsequent audit made after final payment will be refunded to the State.

All expense and accounting records related to the above referenced contract must be maintained for audit purposes for no less than three years beyond the date of final payment, unless a longer term is stated in said contract.

### Recycled Product Use Certification

By signing this form, Contractor certifies under penalty of perjury that a minimum of 0% unless otherwise specified in writing of post consumer material, as defined in the Public Contract Code Section 12200, in products, materials, goods, or supplies offered or sold to the State regardless of whether it meets the requirements of Public Contract Code Section 12209. Contractor specifies that printer or duplication cartridges offered or sold to the State comply with the requirements of Section 12156(e).

### Reminder to Return State Equipment/Property (If Applicable)

(Applies only if equipment was provided by CDPH or purchased with or reimbursed by contract funds)

Unless CDPH has approved the continued use and possession of State equipment (as defined in the above referenced contract) for use in connection with another CDPH agreement, Contractor agrees to promptly initiate arrangements to account for and return said equipment to CDPH, at CDPH's expense, if said equipment has not passed its useful life expectancy as defined in the above referenced contract.

### Patents / Other Issues

By signing this form, Contractor further agrees, in connection with patent matters and with any claims that are not specifically released as set forth above, that it will comply with all of the provisions contained in the above referenced contract, including, but not limited to, those provisions relating to notification to the State and related to the defense or prosecution of litigation.

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**ONLY SIGN AND DATE THIS DOCUMENT WHEN ATTACHING TO THE FINAL INVOICE**

Contractor's Legal Name (as on contract): Children's Hospital & Research Center at Oakland

Signature of Contractor or Official Designee: \_\_\_\_\_ Date: \_\_\_\_\_

Printed Name/Title of Person Signing: \_\_\_\_\_

**CDPH Distribution:** Accounting (Original)      Program



**INSTRUCTIONS FOR CDPH 1204**  
**(Please read carefully.)**

The information on this form will be used by the California Department of Public Health (CDPH) Asset Management (AM) to; (a) conduct an inventory of CDPH equipment and/or property (see definitions A, and B) in the possession of the Contractor and/or Subcontractors, and (b) dispose of these same items. Report all items, regardless of the items' ages, per number 1 below, purchased with CDPH funds and used to conduct state business under this contract. (See *Health Administrative Manual (HAM)*, Section 2-1060 and Section 9-2310.)

The CDPH Program Contract Manager is responsible for obtaining information from the Contractor for this form. The CDPH Program Contract Manager is responsible for the accuracy and completeness of the information and for submitting it to AM.

**Inventory:** List all CDPH tagged equipment and/or property on this form and submit it within 30 days prior to the three-year anniversary of the contract's effective date, if applicable. **The inventory should be based on previously submitted CDPH 1203s**, "Contractor Equipment Purchased with CDPH Funds." AM will contact the CDPH Program Contract Manager if there are any discrepancies. (See HAM, Section 2-1040.1.)

**Disposal:** (*Definition: Trade in, sell, junk, salvage, donate, or transfer; also, items lost, stolen, or destroyed (as by fire).*) The CDPH 1204 should be completed, along with a "Property Survey Report" (STD. 152) or a "Property Transfer Report" (STD. 158), whenever items need to be disposed of; (a) during the term of this contract and (b) 30 calendar days before the termination of this contract. After receipt of this form, the AM will contact the CDPH Program Contract Manager to arrange for the appropriate disposal/transfer of the items. (See HAM, Section 2-1050.3.)

1. List the state/ CDPH property tag, quantity, description, purchase date, base unit cost, and serial number (if applicable) for each item of;
  - A. Major Equipment: **(These items were issued green numbered state/ CDPH property tags.)**
    - Tangible item having a base unit cost of \$5,000 or more and a life expectancy of one (1) year or more.
    - Intangible item having a base unit cost of \$5,000 or more and a life expectancy of one (1) year or more (e.g., software, video.)
  - B. Minor Equipment/Property: **(These items were issued green state/ CDPH property tags.)**

Specific tangible items with a life expectancy of one (1) year or more that have a base unit cost less than \$5,000. The minor equipment and/or property items were issued green unnumbered "BLANK" state/ CDPH property tags with the exception of the following, which are issued numbered tags: Personal Digital Assistant (PDA), PDA/cell phone combination (Blackberries), laptops, desktop personal computers, LAN servers, routers and switches.
2. If a vehicle is being reported, provide the Vehicle Identification Number (VIN) and the vehicle license number to CDPH Vehicle Services. (See HAM, Section 2-10050.)
3. If all items being reported do not fit on one page, make copies and write the number of pages being sent in the upper right-hand corner (e.g. "Page 1 of 3.")
4. The CDPH Program Contract Manager should retain one copy and send the original to: California Department of Public Health, Asset Management, MS1801, P.O. Box 997377, 1501 Capitol Avenue, Sacramento, CA 95899-7377.
5. Use the version on the CDPH Intranet forms site. The CDPH 1204 consists of one page for completion and one page with information and instructions.

For more information on completing this form, call AM at (916) 341-6168.