



**ADOPTED**

BOARD OF SUPERVISORS  
COUNTY OF LOS ANGELES

December 4, 2018

26 December 4, 2018

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The Honorable Board of Supervisors  
County of Los Angeles  
383 Kenneth Hahn Hall of Administration  
500 West Temple Street  
Los Angeles, CA 90012

  
CELIA ZAVALA  
EXECUTIVE OFFICER

Dear Supervisors:

**APPROVAL OF A SUCCESSOR SPONSORED PROGRAMS  
AGREEMENT WITH LOS ANGELES BIOMEDICAL RESEARCH  
INSTITUTE  
(SUPERVISORIAL DISTRICT 2)  
(3 VOTES)**

**SUBJECT**

Approval of a successor Sponsored Programs Agreement with Los Angeles Biomedical Research Institute for the continued provision of medical research and education projects at Harbor-UCLA Medical Center.

**IT IS RECOMMENDED THAT THE BOARD:**

1. Make a determination under Government Code Section 26227 that the work performed by Los Angeles Biomedical Research Institute (LA BioMed) under the successor Sponsored Programs Agreement (Agreement), which includes medical research and education projects at Harbor-UCLA Medical Center (H-UCLA MC) will serve public purposes.
2. Authorize the Director of Health Services (Director), or her designee, to execute the (Agreement LA BioMed, for the continued provision of medical research and education projects at H-UCLA MC, effective upon execution, with a term to continue indefinitely unless terminated by either party in accordance with the termination provisions of the Agreement.
3. Delegate authority to the Director, or her designee, as required by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule, to execute Data Use agreements with LA BioMed and its Sponsored Program Manager for the use and disclosure of information of a limited data set for specified purposes in connection with research activities.

4. Delegate authority to the Director, or her designee, to execute future amendments to the Agreement to incorporate provisions consistent with County ordinance, Board policy, and State/federal requirements, subject to review and approval by County Counsel, with notice to the Board and Chief Executive Office (CEO).

## **PURPOSE/JUSTIFICATION OF RECOMMENDED ACTIONS**

### Background

LA BioMed is a non-profit medical research organization with a long history of administering research and education projects at H-UCLA MC, and a nationally-recognized leader in the field of bringing the findings of basic research to clinical application that include the first test for cholesterol, prevention of blindness in newborns, and development of the first training programs for nurse practitioners. LA BioMed's discoveries benefit the delivery of health care to County patients, and to the medical community and public at large.

LA BioMed's research and education projects are funded by non-County sources such as government and private agencies, public foundations, and individuals. The existing agreement provides LA BioMed with access to H-UCLA MC's facilities, staffing, patients, and medical records to the extent that such access is authorized by the agreement. The current agreement also requires LA BioMed to compensate H-UCLA MC for the use of the hospital's resources by providing "in-kind" services, equipment, and supplies needed by H-UCLA MC at no additional cost.

### Recommendations

Approval of the first recommendation will authorize DHS to make available to BioMed County resources not in use in furtherance of medical research and educational projects to serve public purposes pursuant to the terms of the Agreement.

Approval of the second recommendation will allow the Director, or her designee, to execute a successor Agreement, substantially similar to Exhibit I, with LA BioMed to replace the current agreement that expires December 31, 2018. The recommended Agreement eliminates "in-kind" provisions, and now requires LA BioMed to compensate H-UCLA MC based on defined rate schedules when utilizing hospital resources for non-routine patient care provided during its research studies. The Agreement also recognizes the Department of Health Services (DHS or Department) Research Oversight Board and its authority to ensure that all research projects conducted at H-UCLA MC receive prior approval by the hospital and appropriate medical research committees, and do not adversely impact the hospital's resources for direct patient care. Finally, the Agreement categorizes five levels of research projects based on each category's alignment with DHS' business needs and strategic priorities. These categories will be used to evaluate each research project and DHS' level of support and approval thereof. DHS will partially or fully support Category 1 research, which is anticipated to have a direct impact on clinical operations for a significant number of DHS patients. DHS will provide minimal or no

support for the other four research categories that are determined to have limited or no benefit to DHS or its partners.

Approval of the third recommendation will ensure the confidentiality of protected health information of County patients in accordance with HIPAA and corresponding privacy regulations. In the event that LA BioMed requires a limited data set in connection with a Sponsored Program, DHS will execute a Data Use Agreement with LA BioMed and its Sponsored Program Manager. The successor Agreement provides further patient data protection by including a Business Associate Agreement.

Approval of the fourth recommendation will ensure the Agreement can be amended timely to incorporate applicable County ordinance, Board policy, and State/federal requirements.

### **Implementation of Strategic Plan Goals**

The recommended actions support Strategy II.2, "Support the Wellness of Our Communities" and III.3, "Pursue Operational Effectiveness, Fiscal Responsibility, and Accountability" of the County's Strategic Plan.

### **FISCAL IMPACT/FINANCING**

The Agreement will be substantially cost-neutral, and requires LA BioMed to compensate H-UCLA MC for use of the hospital's resources based on Medi-Cal rates for inpatient care, and Medicare rates plus twenty percent for outpatient care. Such rates will cover DHS' incremental costs. The Agreement also includes a defined rate methodology to assess space and related space-support costs not covered under the separate CEO master lease agreement with LA BioMed, should LA BioMed request additional space. Sponsored Programs of Category 1 research will have minimal fiscal impact since such research is usually non-clinical and does not require costly patient care.

### **FACTS AND PROVISIONS/LEGAL REQUIREMENTS**

The Department has made recent efforts to align its relationships with its principal health care partners, particularly the medical schools and research entities. In the past, the Department has assumed virtually all liability in cases of professional liability (medical care) and certain employment-related liability. The indemnification language in the Agreement reflects a measure of accountability such that each party is responsible for employment-related liability arising from the acts or omissions of its own employees and representatives, and most kinds of professional liability. Recognizing that in some cases, the parties' staff and responsibilities are intermingled, the indemnification language reflects a concept of shared responsibility for certain defense costs (including attorney's fees), and certain professional liability and employment-related liability. In only one kind of circumstance, in which medical care/research is well aligned with the Department's business needs, and strategic priorities and it is anticipated that the results of the research will have significant direct impact for clinical operations for a significant number of the Department's patients, is the Department assuming full professional liability. It is the Department's intent that all business relationships with these principal health care partners include such indemnification language.

The Agreement includes all Board of Supervisors' required provisions, including the most recent provision, Compliance with the County Policy of Equity. The Agreement may be terminated for convenience by County with one-year prior written notice.

County Counsel has approved Exhibit I as to form.

### **CONTRACTING PROCESS**

On June 2, 1981, the Board approved the initial agreement with The Research and Education Institute, Inc., which was subsequently assigned to L.A. Biomed and extended through December 31, 2018 under delegated authority previously approved by the Board. Due to the partnership arrangement with LA BioMed to perform research and education projects at H-UCLA MC, the work under this Agreement is not appropriate for a competitive solicitation.

### **IMPACT ON CURRENT SERVICES (OR PROJECTS)**

Approval of the recommendations will ensure the continuation of Sponsored Programs benefiting the County and its patients, the medical community, and the community at large.

Respectfully submitted,



Christina R. Ghaly, M.D.  
Director

CRG:ck

Enclosure

c: Chief Executive Office  
County Counsel  
Executive Office, Board of Supervisors

# **SPONSORED PROGRAMS AGREEMENT**

**By and Between**

**Los Angeles Biomedical Research Institute  
at Harbor-UCLA Medical Center**

**And**

**County of Los Angeles**

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**SPONSORED PROGRAMS AGREEMENT**

**BY AND BETWEEN**

**THE LOS ANGELES BIOMEDICAL RESEARCH INSTITUTE AT HARBOR-UCLA  
MEDICAL CENTER**

**AND**

**COUNTY OF LOS ANGELES**

This Agreement is entered into this \_\_\_\_\_ day of \_\_\_\_\_, 2018 (the "Effective Date"), by and between County of Los Angeles ("County") and The Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center, a California public benefit not-for-profit corporation (LA BioMed), and replaces in its entirety the Medical Research and Education Agreement No. 201979, and all amendments.

WHEREAS, pursuant to the provisions of Section 1441 of the Health and Safety Code of the State of California, County is operating through its Department of Health Services, under the administrative direction of its Director of Health Services (hereinafter referred to as "Director"), the Harbor-UCLA Medical Center (hereinafter called "Hospital"); and,

WHEREAS, County, in furtherance of its statutory obligation to provide health care services to County residents, has established and operates an accredited hospital and clinic system and graduate medical education program at Los Angeles County Harbor-UCLA Medical Center ("Hospital"); and

WHEREAS, LA BioMed conducts clinical research projects and activities at Hospital that involve direct contact with Hospital patients, access to their personal health information, and/or utilization of Hospital services and resources, originate through Hospital or LA BioMed Workforce Members, and are herein considered "Sponsored Programs" which are funded, in whole or in part, by non-County agencies including LA BioMed, the National Institutes of Health (NIH), organizations, or individuals; and

WHEREAS, the Parties now wish to enter into a new comprehensive agreement to ensure that all Sponsored Programs that includes the use of Hospital facilities or resources are aligned with the Los Angeles County Department of Health Services' (DHS') and Hospital's mission to improve County's health care delivery system, and prior to implementation, that Sponsored Programs receive Hospital and/or DHS approvals, and all Sponsored Programs comply with applicable governmental regulations, and Hospital is compensated for any costs related to Sponsored Program activities that are not part of standard care, unless specifically approved by DHS Research Oversight Board; and

WHEREAS, this Agreement is authorized by California Health and Safety Code § 1441 and Government Code § 26227.

NOW THEREFORE, the Parties hereto agree that LA BioMed and its Workforce Members may implement and perform Sponsored Program activities at Hospital pursuant to the terms of this Agreement.

## 1.0 DEFINITIONS

- 1.1 Agreement.** This Agreement made between County and LA BioMed, including any Exhibits, as may be amended from time to time.
- 1.2 Ancillary Services and Supplies.** Ancillary services and supplies, other than room, board, medical and nursing services, includes services and supplies provided to Hospital patient, which may include, but are not limited to, laboratory, radiology, pharmacy (inpatient only) and physical therapy.
- 1.3 Business Associate** shall have the same meaning as the term "business associate" in 45 C.F.R. 160.103.
- 1.4 CEO.** The Chief Executive Officer of Hospital, or his or her designee.
- 1.6 CMO.** The Chief Medical Officer of the Hospital, or his or her designee i.e., Clinical Research Coordinator.
- 1.7 CMS.** Centers for Medicare and Medicaid Services.
- 1.8 Common Rule.** U.S. Department of Health and Human Services (HHS) Common Rule for the protection of human subjects in Research, codified at 45 CFR 46.101
- 1.9 County.** County of Los Angeles, including as appropriate its departments, facilities and officials.
- 1.10 Covered Entity** shall have the same meaning as the term "covered entity" in 45 C.F.R. 160.103.
- 1.11 Data Use Agreement.** An agreement required by HIPAA's privacy rules between a covered entity and a person or entity that receives a limited data set. The Data Use Agreement must state at a minimum that the recipient will use or disclose the information in the limited data set only for specific limited purposes as set forth in DHS Policy No. 361.19 (De-identification of Protected Health Information/Limited Data Sets) and DHS Policy No. 361.27 (Use and Disclosure of Protected Health Information for Research Purposes) as in effect at any given time.
- 1.12 Department of Health Services (DHS).** County of Los Angeles Department of Health Services.
- 1.13 DHS Research Oversight Board (DHS RB).** A committee or its designee responsible for reviewing select projects submitted by the Hospital or one of the DHS RB members. Responsible for determining DHS support for research activities that are aligned with the DHS mission, per DHS criteria as referenced in Exhibit I (Framework for Research Project Categorization and DHS Resource Support), and overseeing Hospital's approved list of research projects.
- 1.14 Director.** The Director of the County of Los Angeles Department of Health Services, or his or her designee.



- 1.15 FDA.** U.S. Food and Drug Administration.
- 1.16 Federalwide Assurance.** Assurance filed with the Office of Human Research Protections (“OHRP”) within the US Department of Health & Human Services (“HHS”) in compliance with 45 CFR part 46.
- 1.17 Governing Board.** The Los Angeles County Board of Supervisors.
- 1.18 HIPAA.** Health Insurance Portability and Accountability Act of 1996 (HIPAA) is a federal legislation with several provisions. HIPAA provides protections to patients with respect to the privacy of their medical records. HIPAA Title II includes an administrative simplification section which deals with the standardization of healthcare-related information systems. HIPAA Title II seeks to establish standardized mechanisms for electronic data interchange, security, and confidentiality of all healthcare-related data. If an agreement is made with another agency for services at that agency, a Business Associates Addendum or Business Associates Agreement may be required to ensure the maximum security of the protected health information.
- 1.19 Hospital.** The Los Angeles County Harbor-UCLA Medical Center, including all inpatient departments, ancillary services, and outpatient clinics.
- 1.20 Hospital Bylaws and Policies.** Hospital’s medical staff bylaws, medical staff rules and regulations and all policies and procedures adopted by Hospital, as in effect from time to time, to govern the provision of patient care, ethics, occupational health, fire safety, infection control, health information privacy and Sponsored Program compliance.
- 1.21 Informed Consent.** Informed consent means the knowing consent of an individual (or of a legally authorized representative when a vulnerable or dependent person is to be involved) to his or her participation in a surgical or medical procedure without coercion or undue influence. Consent information, oral or written, must be expressed with words and in a language which is understandable to the Sponsored Program Subject or the representative. The text of the consent information must not involve any exculpatory language through which the Sponsored Program Subject is made to waive, or to appear to waive, any legal rights, including release of LA BioMed or its agents from liability for negligence. All Sponsored Program Subjects or their authorized representatives must receive a copy of any consent document which has been completed by them.
- 1.22 Institutional Review Board (IRB).** Institutional review board designated in Hospital’s Federalwide Assurance, including any other duly designated IRB.
- 1.23 Medicare Coverage Analysis (MCA)** is a detailed review required by Medicare of clinical research items, services, procedures and Medicare billing rules to determine the appropriate payer/funding source for each item or service.
- 1.24 Organized Health Care Arrangement** shall have the same meaning as “Organized Health Care Arrangement as contained in 45 CFR §160.103.
- 1.25 Party or Parties.** County or LA BioMed, or both, as appropriate.

- 1.26 Principal Investigator (PI).** Principal investigator is a person authorized by LA BioMed who takes direct responsibility for completion of a Sponsored Program project, directing the Sponsored Program, and reporting directly to the funding agency.
- 1.27 Research.** A systematic, intensive study, designed to increase knowledge or understanding of the subject studied, a systematic Sponsored Program specifically directed toward applying new knowledge to meet a recognized need, or a systematic application of knowledge to the production of useful materials, devices, and systems or methods, including design, development, and improvement of prototypes and new processes to meet specific requirements.
- 1.28 Research Orders.** A template set of medical orders that will be developed by Hospital, for each Sponsored Program, as necessary, using a format that is mutually agreed upon by Hospital and LA BioMed. Sponsored Program Manager and Workforce Members must use Research Orders to request Hospital Services, Ancillary Services or Supplies during the conduct of a Sponsored Program.
- 1.29 Sponsored Program.** Sponsored Program is a program that may receive grants, contracts, gifts, and/or other means of financial assistance in the form of money, property, or both in order to carry out a project or activity under this Agreement, and may be originated by LA BioMed or by one of its Workforce Members and may or may not include research.
- 1.30 Sponsored Agreement.** An agreement between LA BioMed and third parties governing Sponsored Program activities.
- 1.31 Sponsored Program Manager.** Sponsored Program Manager is a Workforce Member, whom LA BioMed has designated to administer and oversee a Sponsored Program, which could include the Principal Investigator or grant manager or other persons deemed appropriate by LA BioMed. If any Sponsored Program involves Sponsored Program Subjects, the Sponsored Program Manager shall have appropriate licenses and certifications.
- 1.32 Sponsored Program Services.** Administrative and clinical services that Hospital offers under this Agreement.
- 1.33 Sponsored Program Subject.** A living person participating in a Sponsored Program which obtains (a) data through intervention or interaction with the person, or (b) identifiable private information. A person may be a human subject when a Sponsored Program obtains data about the person from a third party or from the person directly. A Sponsored Program Subject is a person recruited by the Sponsored Program to participate in a Sponsored Program, and may or may not be a patient who receives medical care at Hospital.
- 1.34 Term.** Term shall have the meaning ascribed to it in Section 5.1.
- 1.35 The Joint Commission.** Formerly known as “The Joint Commission on Accreditation of Healthcare Organizations,” is the accrediting body for health care facilities, or any successor organization.

- 1.36 Workforce Members.** Workforce Members are defined as employees, contractors, volunteers, trainees, students and other persons, whether or not they are paid, whose conduct, is under the direct control of LA BioMed to perform or complete work under this Agreement.

## **2.0 LA BIOMED RESPONSIBILITIES**

- 2.1** As applicable, LA BioMed shall provide Hospital with a listing of the title, LA BioMed IRB number, and Sponsored Program Manager of all Sponsored Programs originated by LA BioMed and/or its Workforce Members, and conducted at Hospital at the time of execution of this Agreement and on a quarterly basis thereafter. LA BioMed will provide Hospital, through CMO, with access to IRB or information relevant to Sponsored Program. Sponsored Programs may or may not include Research, and must be disclosed to CMO.
- 2.2** LA BioMed will obtain the review and approval by CMO and as applicable, DHS RB, of all LA BioMed proposed Sponsored Programs that seek to use Hospital facilities and/or resources prior to initiating such programs at Hospital facilities or with Hospital Resources. LA BioMed will notify CMO when a Sponsored Program that proposes to utilize Hospital patients, their personal health information, or Hospital resources is submitted for review by LA BioMed IRB. LA BioMed will provide CMO with IRB for all such Sponsored Programs for purposes of review, as described in Section 3.1. CMO will notify LA BioMed when a Sponsored Program has received final clearance by Hospital (hereafter “Sponsored Program Approval”). For Sponsored Programs not requiring IRB review but will require hospital facilities or resources, LA BioMed shall also provide CMO access to the Sponsored Program description.
- 2.3** LA BioMed will allow CMO to send representative(s) to meetings of LA BioMed’s IRB for purposes of gaining information on Sponsored Programs that are proposing to use Hospital Services, Ancillary Service or Supplies. LA BioMed should be notified and given the opportunity to review and approve the appointment of any proposed representatives.
- 2.4** LA BioMed will comply with the Common Rule, as applicable to all Sponsored Programs involving human subjects, as defined by Common Rule, for which LA BioMed is responsible, regardless of the source of funding or whether the Sponsored Program is funded. In the case of conflict between regulations of the funding or regulatory agency and HHS, the more restrictive regulations shall prevail. LA BioMed is also obligated by law to adhere to the regulations of the FDA (21 CFR 50.1 and 56.101) governing Sponsored Programs involving investigational new drugs [within the meaning of 21 U.S.C. sections 355(i)(j)], or investigational new devices [within the meaning of 21 U.S.C. section 360(g)].
- 2.5** LA BioMed shall ensure that all LA BioMed-Sponsored Program Workforce Members have the necessary licenses and certifications for Sponsored Program related activity, and have appropriate and current credentials, reported to LA BioMed human resources department, to assure safe and competent Sponsored Programs.
- 2.6 Requirements for Sponsored Programs.** LA BioMed will conduct Sponsored Programs at Hospital, and such Sponsored Programs will be led by a Workforce Member.

- 2.6.1 The Sponsored Program Manager will have overall responsibility for the Sponsored Program, provided that subject to specific Sponsored Program Services requirements, LA BioMed policy (e.g. conflicts of interest in research), and/or as applicable, the requirements of 21 CFR § 54, the Sponsored Program Manager may be required to delegate some of his/her responsibilities to other qualified Workforce Members.
- 2.6.2 Sponsored Program Managers who have obtained final clearance from LA BioMed IRB and have been given access to Hospital approved Research Orders for a Sponsored Program may refer Sponsored Program Subjects to Hospital for clinical services or request use of Hospital's diagnostic, therapeutic, and ancillary resources. Hospital retains sole discretion to prioritize access to its clinical, diagnostic, therapeutic, and Ancillary Services and Supplies.
- 2.6.3 LA BioMed will notify Hospital promptly of any change in a Sponsored Program Manager.
- 2.6.4 As applicable, prior to initiation of a Sponsored Program at Hospital, LA BioMed will create and provide Hospital with access to LA BioMed's Medicare Coverage Analysis (MCA) to allow County to develop its Research Orders for the Sponsored Program. In such MCA, LA BioMed shall make good faith efforts to correctly apply Medicare's rules regarding coverage and payment for services provided to Medicare beneficiaries who are participating in Sponsored Programs involving clinical trials, and shall designate in the MCA which services, if any, LA BioMed believes are covered by Medicare. Sponsored Program Manager and other Workforce Members will be required to use the Research Order or other appropriate documentation as mutually agreed to and developed by both Parties to request Sponsored Program Services and/or Ancillary Services and Supplies from Hospital during the conduct of the Sponsored Program.

Hospital is responsible for billing Medicare and other third party payers, consistently with the Research Orders and MCA. LA BioMed shall pay Hospital for Sponsored Program Services and/or Ancillary Services and Supplies, which are not routine care and which the patient would not have received absent their participation in a Sponsored Program. Hospital will bill LA BioMed accordingly and LA BioMed will reimburse Hospital for the cost of such non-routine care Sponsored Program Services and/or Ancillary Services and Supplies which the patient would not have received absent their participation in a Sponsored Program, Hospital shall have sole responsibility, and any and all liability, for the accuracy of coding determinations and information included on claims submitted by Hospital to Medicare and other third party payers. Hospital will maintain and make available upon request by LA BioMed accurate and appropriate documentation to support all Sponsored Program related claims submitted to LA BioMed.

- 2.6.5 Informed Consent. As applicable, the Sponsored Program Manager will obtain Sponsored Program Subject's Informed Consent that complies with requirements

set forth in 45 CFR, Part 46, Subpart A (Section 46.116); and 21 CFR, Part 50 (Sections 50.20 and 50.25) and California Health and Safety Code Section 24172.

- 2.7 Other Sponsored Program Staff Workforce Members.** LA BioMed will ensure that adequate numbers of qualified Workforce Members are assigned to each Sponsored Program.
- 2.8 Compliance.** The Sponsored Program Manager and all LA BioMed Workforce Members will comply with LA BioMed policies and regulations, Hospital Bylaws and Policies, as applicable, related to Sponsored Program activity at Hospital. In addition, to the extent that federal or State law, or both, require additional approval(s) by federal or State agencies, or by others for the conduct of certain Sponsored Programs, LA BioMed shall assist Sponsored Program Managers in assuring that such approval(s) shall be obtained. The Parties contemplate and intend that any clinical Sponsored Programs that receive such approval may be conducted by Sponsored Program Manager and Workforce Members at Hospital subject to the terms contained herein. Sponsored Programs that do not comply with all applicable, LA BioMed, Hospital, federal, and State policies and regulations will be considered as Unauthorized Sponsored Programs. Unauthorized Sponsored Programs are unacceptable and may result in immediate suspension or termination of Sponsored Program Manager's ability to perform any Sponsored Program at Hospital provided that both parties work together to jointly resolve any perceived dispute or issue regarding a Sponsored Program Manager's activity or conduct in accordance with Section 8.21 (Dispute Resolution). In the event that the parties disagree to resolve such dispute, the CMO and as applicable, DHS RB, shall have the sole discretion to suspend or terminate the Sponsored Program at Hospital.
- 2.9 Access.** County shall grant LA BioMed and Sponsored Program Workforce Members access to Hospital's (1) facility, (2) personnel, to the extent that access to personnel is authorized, (3) patients, medical records and other information required for Hospital to provide Sponsored Program Services for, as well as for Sponsored Program Workforce Members to conduct, in accordance with professional standards, Sponsored Programs, and (4) other services, equipment, supplies and resources of Hospital, as such items will be provided by County in accordance with the terms set forth in the this Agreement. The scope of the access granted under this Agreement shall be subject to compliance with applicable laws, rules and regulations and limited to the extent reasonably required by LA BioMed to perform Sponsored Program activities, as further described hereunder. County does not authorize nor permit Workforce Members to add, delete, copy, transfer, or otherwise take possession or store in either a paper or electronic format any Hospital patient's medical record without prior approval of Hospital and unless LA BioMed and Hospital have entered into a Data Use Agreement. Within one hundred eighty (180) days following execution of this Agreement, the Parties will enter into and execute a mutually acceptable Data Use Agreement.
- 2.10 Utilization of County Personnel.** Except as included in the cost of Sponsored Program Services or Ancillary Services or Supplies requested through Research Orders, or with research related to standard of care billable to Medicare, or with written approval by DHS RB or CMO and/or expressly authorized under the terms of this Agreement, County

employees while on County time shall not be utilized by LA BioMed in the performance of non-standard patient care services hereunder.

## **2.11 Sponsored Program Performance.**

2.11.1 LA BioMed will (and will cause the Sponsored Program Manager to) conduct the Sponsored Program in accordance with this Agreement, the applicable IRB-approved protocol (as amended from time to time), all IRB requirements, all reasonable written instructions of the sponsor (if any), and all applicable laws, regulations and standards; provided, however, the Sponsored Program Manager may deviate from the protocol and such instructions to the extent that the safety, rights and welfare of Sponsored Program Subjects so requires.

2.11.2 Sponsored Programs will commence at Hospital only when the Sponsored Program has received approvals from LA BioMed's IRB and, when applicable, CMO, and DHS RB, including any other approvals required by Hospital.

## **2.12 Records and Reporting.**

2.12.1 Sponsored Program Records. The Sponsored Program Manager will create and maintain records, including case report forms for all Sponsored Program Subjects, in the manner and for the time periods required by the Sponsored Program protocol or sponsor and all state and federal laws and regulations applicable to the Sponsored Program. For studies utilizing Hospital facilities, the Sponsored Program Manager will make such records available to CMO as needed for compliance monitoring to the extent that such records do not contain confidential or proprietary information.

2.12.2 Medical Records. For Sponsored Programs that involve a clinical treatment or diagnostic intervention with Sponsored Program Subjects, the Sponsored Program Manager will place the following in each Sponsored Program Subject's clinical file, in a manner that complies with the applicable requirements of Hospital and The Joint Commission, licensing authorities, CMS and other state and federal laws and regulatory standards:

- a copy of the Sponsored Program Subject's signed Informed Consent form and HIPAA authorization, if required by the IRB (unless Informed Consent form is labeled "DO NOT PLACE IN MEDICAL RECORD");
- a medical record note of enrollment in named Sponsored Program;
- a list of any medication(s) administered as part of a Sponsored Program; and
- notes needed for communication to primary provider care to assure continued safe clinical care, which required notes would be ordered on the Research Orders.

Inclusion of this information in the file does not necessarily imply inclusion in the legal health record or designated record set, which is determined by each institution's policies. The Parties will cooperate to ensure compliance with applicable law and guidance, including but not limited to HIPAA and its implementing regulations, with regard to restriction of Sponsored Program Subjects' access to records during a Sponsored Program and disclosure of records.

2.12.3 Reports. The Sponsored Program Manager will do the following:

- report adverse events as defined by LA BioMed's IRB adverse event reporting procedures, in accordance with Hospital Bylaws and Policies, and if applicable, to Hospital's electronic reporting system for clinical errors or safety risk events, and
- provide the names and medical record numbers of Sponsored Program Subjects at intervals consistent with Hospital Bylaws and Policies.

## **2.13 Acknowledgement and Attribution of Hospital's Contribution**

2.13.1 To the extent feasible, investigators whose Sponsored Programs are performed within Hospital in whole or in part shall acknowledge and provide appropriate attribution to Hospital in all scientific presentations and publications provided that such attribution is not expressly prohibited by the industry sponsor.

Hospital will in whole or in part acknowledge and provide appropriate attribution to LA BioMed when LA BioMed facilities and services are utilized for projects initiated by Hospital affiliates in publications and presentations.

2.13.2 To the extent feasible, LA BioMed-and Hospital will jointly prepare any media press release/advisory, media notification or social media content that announces the findings of any Sponsored Program conducted at Hospital in accordance with the Sponsored Agreement.

2.13.3 LA BioMed-and Sponsored Program Managers reserve the sole right to publish scientific papers in connection with its Sponsored Programs to the extent authorized by federal and State law.

**2.14 Sponsored Program Closeout.** For studies utilizing Sponsored Program Services or Ancillary Services and Supplies, LA BioMed-shall notify CMO at the time that a Sponsored Program is closed or completed.

## **2.15 Sponsored Program Contract Provisions.**

2.15.1 Hospital Not Bound. LA BioMed acknowledges that Hospital will not be bound by provisions in Sponsored Program agreements to which it is not a party, unless County has an opportunity to review such provisions and agrees to them in writing.

**2.16 Debarment and Disqualification.** LA BioMed will not knowingly allow any individual who appears on the FDA Debarment List, is disqualified or restricted as a clinical investigator by the FDA or appears on the Public Health Service Administrative Actions List to provide services related to the Sponsored Program. LA BioMed further represents and warrants that LA BioMed personnel have not been found by the FDA or any other state or federal government agency or enforcement body to have violated any federal, state or local laws, rules or regulations relating to the Sponsored Program. If LA BioMed becomes aware of any relevant disbarment or restriction during the Term, or comes under investigation for conduct related to any Sponsored Program, LA BioMed shall promptly notify Hospital.

**2.17 General Insurance Requirements.** Without limiting LA BioMed indemnification of County and during the Term of this Agreement, LA BioMed shall provide and maintain, and shall require all of its subcontractors to maintain, the following programs of insurance specified in this Agreement. Such insurance shall be primary to and not contributing with any other insurance or self-insurance programs maintained by County, and such coverage shall be provided and maintained at LA BioMed's own expense.

2.17.1 Evidence of Insurance. Certificate(s) or other evidence of coverage satisfactory to County shall be delivered to Director at the: Department of Health Services; Contracts and Grants Division; 313 North Figueroa Street, 6th Floor-East; Los Angeles, California 90012-2659, and to Harbor-UCLA Medical Center; Administration; 1000 W. Carson Street, Room 8E-3, Torrance; California 90509; prior to commencing services under this Agreement. Such certificates or other evidence shall:

2.17.1.1 Specifically identify this Agreement.

2.17.1.2 Clearly evidence all coverages required in this Agreement.

2.17.1.3 Contain the express condition that County is to be given written notice by LA BioMed, to be sent by mail at least thirty (30) calendar days in advance of cancellation for all policies evidenced on the certificate of insurance.

2.17.1.4 To the extent authorized under LA BioMed's insurance coverages, include copies of the additional insured endorsement to the commercial general liability policy, adding County of Los Angeles, its Special Districts, its officials, officers, and employees as insured for all activities arising from this Agreement.

2.17.1.5 LA BioMed's coverage is consistent with commercially reasonable standards or applicable statutes of LA BioMed.

2.17.2 Insurer Financial Ratings. Except as otherwise approved by County, which approval shall not be unreasonably withheld, insurance is to be provided by an insurance company acceptable to County with an A.M. Best rating of not less than A:VII.



- 2.17.3 Failure to Maintain Coverage. Failure by LA BioMed to maintain the required insurance, or to provide evidence of insurance coverage acceptable to County, shall constitute a material breach of contract upon which County may immediately terminate or suspend this Agreement. County may purchase such required insurance coverage, and without further notice to LA BioMed, County may deduct the sums due to LA BioMed any premium costs advanced by County for such insurance.
- 2.17.4 Notification of Incidents, Claims, or Suits. LA BioMed shall report to County:
- 2.17.4.1 Any accident or incident relating to services performed under this Agreement which involve personal injury or property damage and which may result in the filing of a claim or lawsuit against LA BioMed and/or County. Such report shall be made in writing within five (5) days of LA BioMed becoming aware of such incident.
  - 2.17.4.2 Any third party claim which may reasonably be expected to result in the filing of a lawsuit - against LA BioMed regarding a County patient arising from or related to services performed by LA BioMed under this Agreement.
  - 2.17.4.3 Any injury to a Workforce Member which occurs on Hospital property. This report shall be submitted on a County “Non-Employee Injury Report” to County contract manager.
  - 2.17.4.4 Any loss, disappearance, destruction other than in the ordinary course of business, misuse, or theft of County property used, by LA BioMed under the terms of this Agreement.
  - 2.17.4.5 Any accident or incident relating to Sponsored Programs at Hospital which involve personal injury or property damage and which may result in the filing of a claim or lawsuit against another Workforce Member, LA BioMed and/or County that LA BioMed is made aware of. Such report shall be made by LA BioMed promptly upon LA BioMed's receipt of notice of such incidents from a Workforce Member. Notwithstanding any other language set forth herein, the obligations of LA BioMed under this paragraph shall not be deemed to require LA BioMed to disclose any information in violation of the requirements imposed under the bylaws, rules or regulations of Hospital or the IRB or in violation of applicable laws, rules and regulations.
- 2.17.5 Compensation for County Costs. In the event that LA BioMed fails to comply with the insurance requirements of this Agreement, and such failure to comply results in any costs to County, LA BioMed shall pay full compensation for all such costs incurred by County.
- 2.17.6 Insurance Coverage Requirements for Subcontractors. LA BioMed shall ensure any and all subcontractors performing services under this Agreement maintain

insurance coverages, which are consistent with commercially reasonable standards for such subcontracts and meet the insurance requirements of this Agreement that are reasonably applicable to such subcontractor by either:

- 2.17.6.1 LA BioMed providing evidence of insurance covering the activities of subcontractors, or
- 2.17.6.2 LA BioMed providing evidence submitted by subcontractors evidencing that subcontractors providing services under this Agreement maintain the required insurance coverage. County retains the right to obtain copies of evidence of subcontractor insurance coverage at any time.
- 2.17.6.3 Notwithstanding any other language set forth herein, subcontractors subject to, and complying with, the insurance requirements established under the Hospital's medical staff bylaws shall be deemed to be in compliance with the insurance requirements set forth under this Agreement.

## **2.18 Insurance Coverage Requirements.**

2.18.1 General Liability Insurance (written on Insurance Services Office ["ISO"] policy form "CG 00 01" or its equivalent) with limits of not less than the following:

General Aggregate:	\$2 Million
Products/Completed Operations Aggregate:	\$1 Million
Personal and Advertising Injury:	\$1 Million
Each Occurrence:	\$1 Million

2.18.2 Workers Compensation and Employers' Liability insurance providing workers compensation benefits, as required by the Labor Code of the State of California or by any other state, and for which LA BioMed is responsible.

2.18.3 Professional Liability- Research Program. For claims solely related to the Research Program, which do not involve services that are typically provided absent a clinical trial, LA BioMed shall provide Professional Liability Insurance covering liability arising from any error, omission, negligent or wrongful act of LA BioMed, or its officers or employees with limits of not less than \$1 Million per occurrence and \$3 Million aggregate.

## **3.0 COUNTY RESPONSIBILITIES**

**3.1 Institutional Approval of Sponsored Program Applications.** CMO and as applicable, DHS RB, will review all Sponsored Program proposals that seek to use Hospital facilities in accordance with Hospital's policies and procedures. Unless CMO or DHS RB determines otherwise, a Sponsored Program involving a clinical trial will be considered

approved for initiation at Hospital when it has full clearance from LA BioMed IRB and when it has been given access to Hospital approved Research Orders.

- 3.2 Review by CMO and as applicable, DHS RB.** As applicable, three-weeks prior notification should be provided to CMO by LA BioMed that a new Sponsored Program requiring full IRB review is being proposed for conduct at Hospital, and Hospital will notify LA BioMed within ten (10) business days, if a review of a Sponsored Program will be conducted by CMO or as applicable, DHS RB. Hospital will notify LA BioMed of the outcome of the review within ten (10) business days thereafter. Sponsored Program Approval by CMO and as applicable, DHS RB, will be required for final clearance of studies that were identified as subject to further review by CMO, and as applicable, DHS RB. Sponsored Program Approval will be deemed granted if the timelines for review and approval in this Section are not met by Hospital or CMO.
- 3.3 Debarment and Disqualification.** County and LA Biomed will ensure that their Workforce Members do not knowingly include any individual who appears on the FDA Debarment List, is disqualified or restricted as a clinical investigator by the FDA or appears on the Public Health Service Administrative Actions List to provide services related to the Sponsored Program.
- 3.4 Collaborative Sponsored Program Practice Development.** Hospital may include representatives of LA BioMed in all planning activities and standing committees that will involve Sponsored Programs conducted by LA BioMed Workforce Members within Hospital facilities.
- 3.5 County's Obligation for Future Fiscal Years.**

Notwithstanding any other provision of this Agreement, County shall not be obligated for LA BioMed's performance hereunder or by any provision of this Agreement during any of the County's future fiscal years unless and until the Governing Board appropriates funds for this Agreement in County's Budget for each such future fiscal year. In the event that funds are not appropriated for this Agreement, then this Agreement shall be terminated as of June 30 of the last County fiscal year for which funds were appropriated. The Director shall notify LA BioMed in writing of such non-appropriation of funds at the earliest possible date.

- 3.6 Hospital's Insurance Coverage.** Without limiting County's indemnification obligations under this Agreement, County shall provide and maintain insurance coverages and/or programs of self-insurance which are consistent with industry standards and the levels of insurance maintained by other similar county hospitals.

## **4.0 BILLING AND REIMBURSEMENT**

- 4.1 Payment to Hospital.**

4.1.1 LA BioMed shall pay Hospital for Sponsored Program costs incurred by Hospital that are related to Sponsored Program Services, which patient would not have received absent their participating in a Sponsored Program except as

authorized by DHS RB or CMO in support of research that aligns with the DHS mission in which case DHS agrees to provide partial or full support as referenced in Exhibit I. LA BioMed shall reimburse Hospital for the variable cost of such Sponsored Program Services. LA BioMed shall review with CMO the Research Order and confirm acceptance of documented expenses as related to the Sponsored Program, prior to the generation of a bill.

The inpatient reimbursement rate shall be the daily inpatient Medi-Cal per diem rate that is in effect on July 1<sup>st</sup> for that fiscal year. The outpatient and ancillaries rates shall be based upon the Medicare Fee Schedule in effect at the time that such Sponsored Program services were provided to the Sponsored Program participants, plus a 20% administrative fee.

For services or supplies that are not routine care, variable costs shall be billed per Exhibit I. For DHS staff time and effort, including but not limited to information technology services and space and related occupancy, variable costs shall be billed. Information technology services will be billed based upon programmer hours multiplied by the programmer's actual hourly rate, plus variable employee benefits, unless the programmer's time is approved by DHS and funded by LA BioMed. Space and related space support costs will be billed based upon the County CEO Real Estate's fair market value rental rate per square foot and Harbor's utilities cost per square foot, absent other research space lease agreement provisions set forth in the Master Ground Lease Agreement between the parties. LA BioMed shall review such costs with Hospital and confirm acceptance of documented expenses as related to the Sponsor Program, prior to the generation of a bill.

The terms of this §4.1 (Payment to Hospital) shall survive termination of this Agreement.

- 4.1.2 Hospital will bill LA BioMed within one (1) year, or earlier upon notification by LA BioMed requesting an expedited billing, after the Sponsored Program Services were provided to the Sponsored Program as mutually agreed in 4.1.1 above.
- 4.1.3 Payment by LA BioMed to Hospital hereunder shall be made within thirty (30) days after receipt of an invoice and billing statement. LA BioMed will be responsible for payment to Hospital for all Sponsored Program Services and/or Ancillaries and Services and Supplies that the Sponsored Program Subjects receive that are not routine care and which such subjects would not have received absent their participation in a Sponsored Program, except as authorized by DHS RB or CMO. Such Sponsored Program Services and/or Ancillary Services and Supplies must be ordered on a Hospital approved Research Order or other appropriate documentation as mutually agreed to and developed by both Parties.
- 4.1.4 LA BioMed and Hospital will jointly work to ensure appropriate reimbursement occurs in compliance with this Agreement and legal requirements, including Stark and Anti-Kickback. LA BioMed will be responsible for payment to Hospital for non-routine Sponsored Program Services provided by Hospital which the patient

would not have received absent their participation in a Sponsored Program (except as authorized by DHS RBO or CMO for research that aligns with the DHS mission (per Exhibit I), whether or not LA BioMed has received funding or corresponding payment from the sponsor.

- 4.2 Sponsored Program Subject Billing.** LA BioMed is responsible to provide Hospital with MCA and the Hospital is responsible to ensure Sponsored Program Subject's payer source is not billed for Sponsored Program Services that are identified as payable by Sponsor Program's MCA i.e., LA BioMed or Medicare.
- 4.3 Compliance with Deficit Reduction Act of 2005.** Each Party represents that the compensation provided under this Agreement represents the fair market value of the Sponsored Program Services performed by Hospital, has been negotiated in an arm's-length transaction, and has not been determined in any manner with regard to the value or volume of any business or referrals generated.

## **5.0 TERM AND TERMINATION**

- 5.1 Term.** The term of this Agreement shall commence on the "Effective Date" and shall continue in full force and effect, unless otherwise terminated in accordance with the provisions herein (the "Term").
- 5.2 Preservation of Other Remedies.** Failure of non-breaching Party to elect termination under the provisions of this Section 5.0 shall not constitute a waiver of other remedies.
- 5.3 Immediate Termination.** The following shall constitute events of immediate termination, and the non-breaching Party may terminate this Agreement immediately upon providing written notice of breach and immediate termination, or upon such other date as provided in the notice.
- 5.3.1 Patient Safety. Notwithstanding Section 5.7, an incident arises involving the provision (or lack thereof) of services by Workforce Members which is deemed by County to be detrimental to patient safety, or a determination by County that such termination is in the best interest of patient safety and security. Such termination may be in whole or in part provided that County has notified LA BioMed of the incident and provided LA BioMed with an opportunity to cure.
- 5.3.2 Destruction of Premises. Whole or partial destruction during the Term of this Agreement of County Facilities by casualty, if Parties agree that it is thereby rendered unsuitable for the provision of Sponsored Program Services as contemplated, and other suitable facilities are not reasonably available.
- 5.3.3 Improper Consideration. The offer or provision of consideration in any form by LA BioMed, either directly or through an intermediary, to any County officer, employee or agent with the intent of securing this Agreement or securing favorable treatment with respect to the award, amendment or extension of the Agreement or the making of any determinations with respect to LA BioMed performance pursuant to this Agreement. Such improper consideration, among other items, may take the

form of cash, discounts, service, the provision of travel or entertainment, or tangible gifts. LA BioMed shall report any attempt by a County officer or employee to solicit improper consideration for such purposes immediately upon becoming aware of any such attempt. The report shall be made either to County's manager charged with the supervision of the employee or County Auditor-Controller's Employee Fraud Hotline (currently 213/974-0914 or 800/544-6861).

5.3.4 Other Events. Violation of this Agreement of §2.20 (insurance coverage requirements), §8.7 (nondiscrimination in employment), §8.15 (subcontracting), §8.27 (County lobbyists), or violation of LA BioMed's obligations under §4.1 (payment to Hospital).

- 5.4 Termination for Default.** This Agreement may be terminated by either Party in the event that the other Party breaches the material terms of this Agreement and fails to cure any such breach within a ten (10) business day period, or such longer period as approved in writing by the non-breaching Party, following receipt of notice from the non-breaching Party regarding such breach. The non-breaching Party's failure to exercise this right of termination shall not constitute a waiver of such right, which may be exercised at any subsequent time. Without limiting the generality of the foregoing, failure of LA BioMed to maintain compliance with the requirements set forth in this §5.4 (termination for default) shall constitute default under this Agreement. Without limiting the rights and remedies available to County under any other provision of this Agreement, failure of LA BioMed to cure such default within ten (10) business days of notice, or such longer period as approved in writing by County, shall be grounds upon which County may terminate this Agreement.
- 5.5 Termination for Convenience.** The performance of services under this Agreement may be terminated with or without cause in whole or in part at any time when such action is deemed by County to be in its best interest upon one (1) year advance notice specifying the extent to which performance of services under this Agreement is terminated and the date upon which such termination becomes effective.
- 5.6 Termination of Services by LA BioMed.** Notwithstanding anything to the contrary, LA BioMed may terminate the provision of services with respect to any Sponsored Program immediately upon: (1) written notice to County upon LA BioMed's or the Hospital's IRB's identification of any medical risk to Sponsored Program Subjects, as applicable; (2) receipt of notice of regulatory action by the FDA terminating or suspending that medical Research Sponsored Program; or (3) termination of the Sponsored Program by the sponsor. County shall inform LA BioMed immediately in the event that County determines that any Sponsored Program safety concern exists so that LA BioMed may determine whether termination is appropriate. In addition, LA BioMed may terminate this Agreement at any time, without cause, upon ninety (90) days prior written notice to County.
- 5.7 Suspension of Sponsored Program by CMO.** Notwithstanding Section 5.3.1, in the event CMO finds that any activity conducted by Workforce Members at Hospital endangers the health or safety of County patients, County personnel, or others, LA BioMed shall request such Workforce Members to suspend such activity immediately upon LA BioMed's receipt of a written notice from CMO to LA BioMed CEO and PI/Workforce

Member. In addition, LA BioMed shall agree that CMO may close or secure the premises where the activity has been conducted until such time as the activity is reasonably determined to be safe or, when hazardous, until such time that the premises are reasonably determined to be non-hazardous to County patients, County workers, and others.

- 5.8 Survival.** The following provisions of this Agreement shall survive its termination and expiration: §2.17 (general insurance requirements), §2.18 (insurance coverage requirements), §6.2 (records and audit), §7.0 (indemnification), §8.2 (confidentiality), §8.15 (subcontracting), §8.17 (governing law; entire agreement), §8.25 (indemnification for fair labor standards), §8.26 (indemnification for employment eligibility verification), and §8.32 (investigations).

## **6.0 REPORTING AND ACCOUNTABILITY**

- 6.1 General Operations.** Each Party shall collect and maintain accurate information on the nature and scope of its operations in County facilities and provide such information as reasonably requested by the other Party

### **6.2 Records and Audits.**

6.2.1 Financial and Time Keeping and Other Records. LA BioMed shall prepare and maintain accurate and complete financial and other operational/business records of the Sponsored Program Services in accordance with LA BioMed policies.

6.2.2 Federal Access to Records. If, and to the extent that, Section 1861(v)(1)(I) of the Social Security Act [42 U.S.C. Section 1395x(v)(1)(I)] is applicable, LA BioMed agrees that for a period of five (5) years following the expiration or termination of this Agreement, or as otherwise required by law, LA BioMed shall maintain and make available, upon written request, to the Secretary of the United States Department of Health and Human Services or the Comptroller General of the United States, or to any of their duly authorized representatives, the contract, books, documents and records of LA BioMed which are necessary to verify the nature and extent of the cost of services provided hereunder. Furthermore, if LA BioMed carries out any of the services provided hereunder through any subcontract with a value or cost of Ten Thousand Dollars (\$10,000) or more over a twelve-month period with a related organization (as that term is defined under Federal law), LA BioMed agrees that each such subcontract shall provide for such access to the subcontract, books, documents and records of the subcontractor. In the event that such request for access is made by any representative of the Federal government, LA BioMed shall notify County in writing within five (5) business days of receipt of such request.

6.2.3 Audit Reports. In the event that any Federal or State auditor conducts an audit of LA BioMed and such audit directly concerns or has a material effect on any of the Sponsored Program Services, LA BioMed shall file a copy of any final audit report prepared by such auditor with County's Auditor-Controller within thirty (30) days

of receipt thereof to the extent permitted under this Agreement, or under applicable State or Federal law or regulations.

- 6.2.4 Audit/Compliance Review. During the Term or within five (5) years after expiration or termination of this Agreement, authorized representatives of County may conduct an audit, upon advance written notice, during normal business hours, of LA BioMed's performance of the services provided under this Agreement. In the event County representatives conduct an audit/compliance review of LA BioMed, LA BioMed shall cooperate fully with County's representatives. LA BioMed shall allow County representatives reasonable access to all non-attorney/client privileged records of services rendered and all financial, medical and other records that directly concern or may have a material effect on services provided by LA BioMed under this Agreement and shall allow photocopies to be made of these documents using LA BioMed's photocopier, for which County shall reimburse LA BioMed promptly for its customary charge for record copying services, if requested. Information obtained through an audit/compliance review shall be subject to the confidentiality requirements of §8.2 (Confidentiality). County shall provide LA BioMed with at least fifteen (15) working days prior written notice of any audit/compliance review.

LA BioMed shall have the opportunity to review County's audit findings, and LA BioMed shall have thirty (30) days after receipt of County's audit/compliance review results to submit documentation to County to resolve any audit exceptions. For any audit exceptions unresolved to County's reasonable satisfaction following this thirty (30) day period, County may apply the exception rate found in the audit or statistical sample of LA BioMed's total payment to County. If LA BioMed chooses to appeal County's application of an audit exception rate under this §6.2.4 (audit/compliance review), LA BioMed shall submit documentation for review by the Director within thirty (30) days after application of the exception rate.

- 6.2.5 Audit Settlements. Nothing in this Agreement shall restrict the right of County or LA BioMed to pursue any claims for repayment or additional payment based on the results of an audit/compliance review conducted under §6.2.4 (audit/compliance review). In the event any third-party reimbursement to County, whether by Medicare, Medi-Cal, Medi-Cal/Short Doyle, private or other payers, is denied or reduced due to LA BioMed's failure to provide the documents set forth in this Agreement for a period of five (5) years following the expiration or termination of this Agreement, LA BioMed shall indemnify County for such losses. Such losses include denial or reduction with respect to individual claims, cost report disallowances, or others.
- 6.2.6 Failure to Comply. Failure of LA BioMed to comply with the provisions of this §6.2 (records and audits) shall constitute a material breach of this Agreement. If such breach is not remedied within ninety (90) days following receipt of written notice from County, then it shall become an event of termination for cause pursuant to §5.4 (termination for cause).



- 6.2.7 Inspection. If any governmental or regulatory authority notifies Hospital that the authority will, in connection with Sponsored Programs at the Hospital, inspect Hospital's records, facilities, equipment or procedures, or otherwise take action related to the Sponsored Program, County shall promptly notify LA BioMed and allow LA BioMed representatives to be present at the inspection/action and participate in any response to the inspection/action to the extent permitted by law. County shall provide LA BioMed with copies of any reports issued by the authority and County's proposed response.
- 6.2.8 Review Rights. In order to ensure compliance with this Agreement and any Sponsor Agreements, LA BioMed may need access to information maintained by County. Upon request by authorized LA BioMed personnel, County shall provide to LA BioMed, in a timely manner as mutually agreed by the Parties, access to records for any Sponsored Program Subjects for whom services have been provided at Hospital pursuant to this Agreement. County shall cooperate with such authorized LA BioMed personnel in such review.

## 7.0 INDEMNIFICATION

### 7.1 Professional Liability Indemnification.

- 7.1.1 By County. Except as set forth below, to the extent permitted by law and specifically with the exception of claims of fraud and/or punitive damages, County shall indemnify, defend and hold harmless LA BioMed and its officers, employees, agents, students, fellows, volunteers and Faculty from and against any and all losses, claims, damages, liabilities and expenses, of every conceivable kind, character, and nature (collectively, "Claim") arising out of or connected with, either directly or indirectly, any negligent act or omission or allegedly negligent act or omission in rendering of, or failure to render, health care services or treatment by LA BioMed and its officers, employees, agents, students, fellows, volunteers and Faculty at Hospital in the conduct of research as set forth in this Agreement, Exhibit I, Category 1, provided that the conditions of indemnification in Section 7.6 herein are met.
- 7.1.2 Shared Responsibility for Certain Claims. The County shall not be obligated to defend or indemnify LA BioMed and its officers, employees, agents, students, fellows, volunteers and Faculty from and against any Claim arising out of or connected with, either directly or indirectly, the conduct of research as set forth in this Agreement, Exhibit I, Category 1, and further shall not be obligated to defend or indemnify LA BioMed and its officers, employees agents, students, fellow, volunteers and Faculty from and against any Claim arising out of or connected with, either directly or indirectly, any violation, or allegations of a violation, of County policy, rules and/or regulations, including DHS and Hospital policies, and such violation is committed, or alleged to be committed, by LA BioMed Personnel not employed by the County at the time the acts or omissions giving rise to the Claim occurred. Rather, it is the intention and the agreement of the parties to share Certain Defense Fees and Costs (as defined below), and indemnity obligations for any

violation, or allegations of a violation, of County policy, rules and/or regulations, including DHS and Hospital policies, and such violation is committed, or alleged to be committed, by Hospital Personnel not employed by the County at the time the acts or omissions giving rise to the Claim occurred.

An apportionment of what percentage shall be borne by LA BioMed, and what percentage shall be borne by the County shall be based on the mutual written agreement of the parties, negotiated and determined in good faith, or in the absence of agreement, in the manner set forth below. In the absence of such written apportionment agreement, the parties agrees as follows:

- 7.1.2.1 The parties shall evenly split (50/50) Certain Defense Fees and Costs, with payment to be made on a monthly basis within forty-five days following presentation of an invoice prepared by the party seeking payment that specifies the total amount of legal fees and costs.
- 7.1.2.2 The parties shall evenly split (50/50) the cost of any settlement, judgment or award, including any award of costs and attorneys' fees for such claim, except with respect to any award of punitive damages, which shall remain the sole liability of the party(ies) subject to such award (the "Professional Liability Indemnity Payments").
- 7.1.2.3 Within sixty (60) days of the conclusion of a Claim subject to this Section 7.1.2, any party timely complying with its obligations under Sections 7.2.3.1 and 7.2.3.2, as they came due, may request an equitable apportionment of the parties' respective liability for Certain Defense Fees and Costs and/or Professional Liability Payments. Such apportionment shall be made by a single arbitrator applying common and statutory law as well as principles of equity, and shall be final, conclusive and binding on all parties. The arbitrator shall set forth his or her determination in a written reasoned decision, and any amounts due and owing thereunder shall be paid within thirty (30) days thereof. Each party shall bear its own attorneys' fees and costs of the arbitration, except that the fee of the arbitrator shall be evenly split (50/50) between the parties. Before resorting to arbitration, the parties agree to endeavor in good faith to settle the dispute by way of private mediation. Each party shall bear its own attorney's fees and costs of the mediation, except that the fee of the mediator shall be evenly split (50/50) between the parties. The mediation process shall be confidential based upon terms acceptable to the mediator.
- 7.1.2.4 For purposes of Section 7.1.2, Certain Defense Fees and Costs shall mean any Claim arising out of or connected with, either directly or indirectly, (a) any violation, or allegations of a violation, of County policy, rules and/or regulations, including DHS and Hospital policies, and such violation is committed, or alleged to be committed, by LA BioMed Personnel not employed by the County at the time the acts or omissions giving rise to the Claim occurred; or (b) such Claim arises out of or from the failure, or

allegation of a failure, to appropriately supervise staff, and only in the instance where only LA BioMed or the County is the defendant in such litigation.

## 7.2 Indemnification for Employment Practices.

- 7.2.1 By County. To the extent permitted by law and specifically with the exception of punitive damages, County shall indemnify, defend and hold harmless LA BioMed and its officers, employees, agents, students, fellows, volunteers and Faculty from and against any and all losses, claims, damages, liabilities and expenses, including reasonable attorneys' fees and costs, of every conceivable kind, character, and nature for an Employment Practices Claim arising out of or connected with, either directly or indirectly, (a) the employment or employment practices of County Personnel who received no compensation of any kind from LA BioMed at the time of action or inactions giving rise to the Employment Practices Claim, and (b) arising out of or connected with, either directly or indirectly, the provision of services under this Agreement.

An Employment Practices Claim shall mean a written demand or claim arising out of or related to an Employment Practices Wrongful Act. An Employment Practices Wrongful Act shall mean any actual or alleged violation of any common or statutory law concerning employment discrimination, harassment, wrongful termination, hostile work environment, employment related defamation, or any other employment-related damage Claim.

- 7.2.2 By LA BioMed. To the extent permitted by law and specifically with the exception of claims of fraud and/or punitive damages, LA BioMed shall indemnify, defend and hold harmless County and its officers, employees, agents, students, fellows and volunteers from and against any and all losses, claims, damages, liabilities and expenses, including reasonable attorneys' fees and costs, of every conceivable kind, character, and nature for an Employment Practices Claim arising out of or connected with, either directly or indirectly the employment or employment practices of LA BioMed personnel who are not Concurrent Employees as defined in Section 7.2.3.

- 7.2.3 Shared Responsibility for Employment Practices Claims Related To Employment Wrongful Acts By Concurrent Employees. Neither party shall be obligated to defend or indemnify the other party for an Employment Practices Claim arising out of connected with, either directly or indirectly, Employment Wrongful Acts committed by any individual who is concurrently a County Personnel and LA BioMed Personnel at the time of actions or inactions giving rise to the claim ("Concurrent Employees"), except as set forth herein. It is the intention and the agreement of the parties to share Certain Defense Fees and Costs (as defined below), and indemnity obligations, for Employment Practices Claims arising from Employment Wrongful Acts committed by person(s) who are concurrently County Personnel and LA BioMed Personnel at the time the acts or omissions giving rise to the Claim occurred. An apportionment of what percentage shall be borne by LA

BioMed, and what percentage shall be borne by the County shall be based on the mutual written agreement of the parties, negotiated and determined in good faith, or in the absence of agreement, in the manner set forth below. In the absence of such written apportionment agreement, the parties agree as follows:

7.2.3.1 The Parties shall evenly split (50/50) Certain Defense Fees and Costs, with payment to be made on a monthly basis within forty-five days following presentation of an invoice prepared by the party seeking payment that specifies the total amount of legal fees and costs.

7.2.3.2 The Parties shall evenly split (50/50) the cost of any settlement, judgment or award, including any award of costs and attorneys' fees for such claim, except with respect to any award of punitive damages, which shall remain the sole liability of the party(ies) subject to such award (the "Employment-Related Indemnity Payments").

7.2.3.3 Within sixty (60) days of the conclusion of the Employment Practices Claim, any party timely complying with its obligations under Sections 7.2.3.1 and 7.2.3.2, as they came due, may request an equitable apportionment of the parties' respective liability for Certain Defense Fees and Costs and/or Employment-Related Indemnity Payments. Such apportionment shall be made by a single arbitrator applying common and statutory law as well as principles of equity, and shall be final, conclusive and binding on all parties. The arbitrator shall set forth his or her determination in a written reasoned decision, and any amounts due and owing thereunder shall be paid within thirty (30) days thereof. Each party shall each bear its own attorneys' fees and costs of the arbitration, except that the fees of the arbitrator shall be evenly split (50/50) between the parties. Before resorting to arbitration, the parties agree to endeavor in good faith to settle the dispute by way of private mediation. Each party shall bear its own attorney's fees and costs of the mediation, except that the fee of the mediator shall be evenly split (50/50) between the parties. The mediation process shall be confidential based upon terms acceptable to the mediator.

7.2.3.4 For purposes of Section 7.2.3, Certain Defense Costs and Fees shall mean all legal fees and costs incurred by either County or University as a result of an Employment Practices Claim arising from Employment Wrongful Acts committed by one or more persons who are concurrently County Personnel and University Personnel at the time the acts or omissions giving rise to the Claim occurred, and only in the instance where only the University or the County is the defendant in such litigation.

7.3 No Requirement to Defend or Indemnify with Regard to Administrative Proceedings. Neither County nor LA BioMed shall be obligated to provide for the defense of any administrative or criminal proceedings brought against any current or former employee of LA BioMed, any current or former employee of County, or any employee concurrently or

formerly employed by both County and LA BioMed. Neither County nor LA BioMed shall be obligated to indemnify any current or former employee of County or any employee concurrently or formerly employed by both County and LA BioMed with regard to costs and expenses associated with such defense. For purposes of this Section 7.4 "administrative proceeding" shall mean any non-judicial proceeding brought by or before any government or administrative agency, including but not limited to proceedings before the Medical Board of California.

#### 7.4 General Indemnification

7.4.1 By County. To the extent not covered by the other indemnification provisions set forth in Section 7.0, and to the extent permitted by law and specifically with the exception of claims of fraud and/or punitive damages, County shall indemnify, defend and hold harmless LA BioMed and its officers, employees, agents, students, fellows and volunteers from and against any and all losses, claims, damages, liabilities and expenses, including reasonable attorneys' fees and costs, of every conceivable kind, character, and nature, including bodily injury, death, personal injury, property damage or worker's compensation arising out of or connected with, directly or indirectly, County's operations or any activities conducted by, through or on behalf of County at County facilities, in the performance of County's obligations hereunder.

7.4.2 By LA BioMed. To the extent not covered by the other indemnification provisions set forth in Section 7.0, and to the extent permitted by law and specifically with the exception of claims of fraud and/or punitive damages, LA BioMed shall indemnify, defend and hold harmless County and its officers, employees, agents, students, fellows and volunteers from and against any and all losses, claims, damages, liabilities or expenses, including reasonable attorneys' fees and costs, of every conceivable kind, character, and nature, including bodily injury, death, personal injury, property damage or worker's compensation arising out of or connected with, either directly or indirectly, LA BioMed's operations or any activities conducted by, through or on behalf of LA BioMed.

#### 7.6 Conditions for Indemnification

7.6.1 Conditions for Defense and Indemnity by County. The following conditions shall apply to any and all of County's defense and indemnity obligations in this Agreement: (a) LA BioMed shall give prompt notice to County of any action or claim for which it seeks defense or indemnification; and (b) LA BioMed and its officers, employees, agents, students, fellows, volunteers and Faculty receiving such defense and/or indemnification from County shall fully cooperate with County in any defense, settlement or other disposition of any claim or action for which defense or indemnification is being provided. County shall retain full authority to settle such claims for such amounts and in such circumstances as County determines to be in its best interests, and to direct all litigation from the creation of a discovery plan through any trial and/or appeal, including acting as first chair in

trial, notwithstanding any election by LA BioMed to retain, at its sole cost and expense, separate counsel for such action or claim.

7.6.2 Conditions for Defense and Indemnity by LA BioMed. The following conditions shall apply to any and all of LA BioMed's defense and indemnity obligations in this Agreement: (a) County shall give prompt notice to LA BioMed of any action or claim for which it seeks defense or indemnification; and (b) County and its officers, employees, agents, students, fellows and volunteers receiving such defense and/or indemnification from LA BioMed shall fully cooperate with LA BioMed in any defense, settlement or other disposition of such claim or action. LA BioMed shall retain full authority to settle such claims for such amounts and in such circumstances as LA BioMed determines to be in its best interests, and to direct all litigation from the creation of a discovery plan through any trial and/or appeal, including acting as first chair in trial, notwithstanding any election by County to retain, at its sole cost and expense, separate counsel for such action or claim.

## **8.0 ADDITIONAL PROVISIONS**

**8.1 Notices.** Unless otherwise specified in this Agreement, any notice, document, or other communication given or made hereunder shall be in writing and shall be deemed given upon (i) hand delivery or (ii) deposit of the same in the United States registered or certified mail, first-class postage and fee prepaid, and correctly addressed to the Party for whom it is intended at the following addresses:

If to County:

Chief Medical Officer  
County of Los Angeles Department of Health Services  
313 North Figueroa Street, Room 908  
Los Angeles, California 90012

with a copy to:

Office of County Counsel  
Attn: Health Services Division  
500 West Temple Street, 6<sup>th</sup> Floor  
Los Angeles, California 90012

Kathy K. Hanks, Director, Contracts and Grants Division  
County of Los Angeles Department of Health Services  
313 N. Figueroa St., 6<sup>th</sup> Floor East  
Los Angeles, CA 90012

If to LA BioMed:

Los Angeles Biomedical Research Institute at  
Harbor-UCLA Medical Center  
1124 Carson Street  
Torrance, CA 90502  
Attn: President and CEO

With a copy to:

Los Angeles Biomedical Research Institute at Harbor-UCLA  
Medical Center  
1124 W Carson Street  
Torrance, CA 90502  
Attn: LA BioMed Executive Vice President, Operations

or at such other place or places as may from time to time be specified in a notice similarly given. Each Party shall at all times keep the other Party notified of its current address and shall promptly notify the other Party of any change of address.

- 8.2 Confidentiality.** Notwithstanding any other provision of this Agreement, LA BioMed and County shall maintain the confidentiality of all records and information, including billings, LA BioMed reports, audit reports, County records and patient records, as required by applicable Federal, State and local laws, ordinances, rules, regulations and directives (including DHS' policy, and Hospital's Medical Staff Rules and Regulations with respect to Sponsored Program Services provided at Hospital) relating to confidentiality. LA BioMed and County shall make reasonable efforts to inform all of their officers, employees, agents, independent contractors and others providing services hereunder of the confidentiality provisions of this Agreement.
- 8.3** Health Insurance Portability and Accountability Act of 1996 (HIPAA). County is subject to the Administrative Simplification requirements and prohibitions of the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191 (HIPAA), and regulations promulgated thereunder, including the Privacy, Security, Breach Notification, and Enforcement Rules at 45 Code of Federal Regulations (C.F.R.) Parts 160 and 164 (collectively, the "HIPAA Rules"). Under this Agreement, LA BioMed provides services to County and LA BioMed creates, has access to, receives, maintains, or transmits Protected Health Information as defined in Exhibit II in order to provide those services. County and LA BioMed therefore agree to the terms of Exhibit II - Business Associate Under Health Insurance Portability and Accountability Act of 1996 (HIPAA).
- 8.4 Rules and Regulations.** During the time that Workforce Members are at Hospital, such persons shall be subject to the rules and regulations of Hospital. The Director's administrator at Hospital shall furnish to LA BioMed a copy of Hospital's rules and regulations which are applicable to LA BioMed prior to the execution of this Agreement, and during the Term shall furnish LA BioMed with any changes thereto as from time to time may be adopted. It is the responsibility of LA BioMed to acquaint itself and such persons who may provide services hereunder with all such rules and regulations, as

provided by Director's administrator at Hospital. Upon receipt of notice from County, LA BioMed shall take such corrective action with respect to any Workforce Member who LA BioMed determines after reasonable investigation does not comply with such rules and regulations; provided, however, that at the written request of County, LA BioMed will permanently withdraw any of its Workforce Members, from the provision of services hereunder in the event that the Director, in consultation with LA BioMed, determines that: (1) any such Workforce Member has violated such rules or regulations, or (2) such Workforce Member's actions, while on County premises, indicate that such Workforce Member may adversely affect the delivery of health care services at the Hospital. Prior to requesting such removal, the Director must submit with such written notice a written statement of the facts supporting any such alleged violation or action and must reasonably consult with LA BioMed to determine whether appropriate action should be taken. Nothing contained in this Agreement shall affect any rights which may be available to Workforce Members under LA BioMed's IRB.

## **8.5 Reports and Documentation.**

8.5.1 County agrees to provide LA BioMed and Sponsored Program Managers with timely notice of any adverse events involving County patients participating in Sponsored Programs.

8.5.2 County agrees that Hospital shall provide LA BioMed with information concerning Hospital and participation by Hospital in Sponsored Programs as reasonably required by LA BioMed to comply with applicable law or contractual obligations under Sponsor Agreements. Hospital shall further ensure that participation by County patients in Sponsored Programs is documented and records are maintained in accordance with applicable laws.

**8.6 Nondiscrimination in Services.** LA BioMed shall not discriminate in the provision of services hereunder because of race, color, religion, national origin, ancestry, sex, age, sexual orientation, or physical or mental disability, in accordance with requirements of Federal and State law and County policy. LA BioMed shall use reasonable efforts to ensure that intended beneficiaries of this Agreement are provided services without regard to race, color, religion, national origin, ancestry, sex, age, sexual orientation, or physical or mental disability.

## **8.7 Nondiscrimination in Employment.**

8.7.1 Nondiscrimination. LA BioMed certifies and agrees that its policy is that all persons employed by it, its affiliates, subsidiaries or holding companies are and shall be treated equally by it without regard to, and shall not be discriminated against because of, race, color, religion, ancestry, national origin, sex, age, sexual orientation, or physical or mental disability, in compliance with all anti-discrimination laws and regulations of the United States of America and the State of California as they now exist or may hereafter be amended.

8.7.2 Employment Status. LA BioMed shall make every effort to ensure it employs qualified applicants, and treats employees during employment, without regard to



race, color, religion, ancestry, national origin, sex, age, sexual orientation, or physical or mental disability, nor shall LA BioMed discriminate against such applicants or employees because of such characteristics; all in compliance with all applicable anti-discrimination laws and regulations of the United States of America and the State of California as they now exist or may hereafter be amended. Such action shall include the following: employment, upgrading, demotion, transfer, recruitment or recruitment advertising, lay-off or termination, rates of pay or other forms of compensation, and selection for training, including apprenticeship.

8.7.3 Vendors. LA BioMed shall not discriminate against any subcontractor, bidder, or vendor on the basis of race, color, religion, ancestry, national origin, sex, age, sexual orientation, or physical or mental disability, as required by all applicable anti-discrimination laws and regulations of the United States of America and the State of California as they now exist or may hereafter be amended.

8.7.4 Verification. LA BioMed shall allow County representatives access to its employment records during regular business hours upon advance written notice to verify compliance with these provisions when so requested by County. Prior to any such inspection, LA BioMed may remove personal employee information from such records, which is protected under the privacy laws of the State of California. To the extent any such information may come into the possession of County during such an inspection, County hereby promises to protect same from disclosure to third parties.

8.7.5 Breach. Violation of any provisions under this §8.7 (nondiscrimination in employment) shall constitute an event of immediate termination pursuant to §5.4 (termination for cause) of this Agreement. County reserves the right to determine independently that the anti-discrimination provisions of this Agreement have been violated. A determination by the California Fair Employment Practices Commission or the Federal Equal Employment Opportunity Commission that LA BioMed has violated State or Federal anti-discrimination laws or regulations shall constitute a finding by County that LA BioMed has violated anti-discrimination provisions of this Agreement.

8.7.6 Any Sponsored Program Manager or designee conducting unauthorized Sponsored Programs are subject to immediate termination of such unauthorized Sponsored Programs, including revocation of Sponsored Program privileges at Hospital and referral to the IRB, attending staff association, LA BioMed or County leadership for corrective personnel action as appropriate.

**8.8 Workforce Member Performance While Under the Influence.** LA BioMed shall use its reasonable efforts to ensure that none of its Workforce Members shall perform services hereunder while under the influence of any alcoholic beverage, medication, narcotic or other substance that might impair his or her physical or mental performance.

**8.9 LA BioMed Performance during Disaster or Civil Unrest.** LA BioMed recognizes that health care facilities maintained by County, including shelters and relief facilities operated

by County during a disaster, provide care essential to the population of the communities they serve and that these services are of particular importance at the time of a natural disaster or other similar event, or at the time of a riot, insurrection or civil unrest. Notwithstanding any other provision of this Agreement, LA BioMed shall continue to provide services at County facilities during any natural disaster or other similar event, riot, insurrection or civil unrest, so long as such performance remains physically possible and does not subject Workforce Members to unreasonable threat to personal safety. Failure to comply with this requirement shall be considered an event of termination for cause pursuant to §5.4 (termination for cause) of this Agreement. Parties shall work together to develop a plan for the provision of services in the event of a disaster or civil unrest.

**8.10 Licenses, Permits, Registrations and Certificates.** LA BioMed and County, respectively, shall obtain and maintain during the Term all appropriate licenses, permits, registrations and certificates required by law for the provision of their respective services hereunder. LA BioMed shall require that all its Workforce Members, including all its independent contractors, who perform services hereunder obtain and maintain in effect during the Term, all licenses, permits, registrations and certificates required by law which are applicable to their performance hereunder. Copies of all such licenses, permits, registrations and certifications shall be made available to County or LA BioMed, respectively, upon request.

**8.11 Unlawful Solicitation.** LA BioMed shall inform all of its officers, employees and agents, including all its independent contractors, providing services hereunder in writing of the provisions of Article 9 of Chapter 4 of Division 3 (commencing with Section 6150) of the Business and Professions Code of the State of California (i.e., State Bar Act provisions regarding unlawful solicitation as a runner or capper for attorneys) and shall use reasonable efforts to ensure that there is no violation of said provisions by its officers, employees, agents and independent contractors. LA BioMed agrees that if a patient requests assistance in obtaining the services of any attorney, it shall use reasonable efforts to refer the patient to the attorney referral services of all those bar associations within County or the appropriate County agency that have such a service.

A copy of such written notice shall be retained by LA BioMed for purposes of inspection and audit and made available to County upon reasonable written request.

**8.12 Conflict of Interest.** No County officer or employee whose position in County enables him or her to influence the award of this Agreement or any competing agreement and/or no officer, employee, agent, or independent contractor of LA BioMed who may financially benefit from the provision of services hereunder shall in any way participate in County's approval process for the award of this Agreement or any competing agreement, or ongoing evaluation of such services, under this Agreement or any competing agreement, or in any way attempt to unlawfully influence County's approval or ongoing evaluation of such services.

LA BioMed shall comply with all conflict of interest laws, ordinances and County regulations now in effect or hereafter to be enacted during the Term. LA BioMed represents that it is not now aware of any facts which create a conflict of interest. If LA BioMed hereafter becomes aware of any facts which might reasonably be expected to

create a conflict of interest, it shall promptly make a full written disclosure of such facts to County. Full written disclosure shall include, without limitation, identification of all persons involved and a complete description of all relevant circumstances.

### **8.13 Representation against Contingent Fees.**

8.13.1 Representation. LA BioMed represents that no person or selling agency has been employed or retained to solicit or secure this Agreement upon an agreement or understanding for a commission, percentage, brokerage or contingent fee, excepting bona fide employees or bona fide established commercial or selling agencies maintained by LA BioMed for the purpose of securing business.

8.13.2 Remedy. Breach or violation of this representation shall constitute an event of termination for cause, pursuant to §5.4 (termination for cause). In addition to the remedies provided in this Agreement, County in its sole discretion shall be permitted to deduct from payments made under this Agreement, or otherwise recover, the full amount of such commission, percentage, brokerage or contingent fee.

**8.14 Delegation and Assignment.** Neither LA BioMed nor County shall delegate its duties or assign its rights hereunder, either in whole or in part, without prior written consent of the other Party. Any delegation or assignment which does not have such consent shall be null and void. For purposes of this §8.14 (delegation and assignment), consent shall require a written amendment to this Agreement which is formally approved and executed by the Parties. Any billings to County by any delegate or assignee on any claim under this Agreement, absent County's consent, shall not be paid by County.

**8.15 Subcontracting.** No performance of this Agreement, or any portion thereof, shall be subcontracted by either Party without the prior written consent of the other Party, as provided in this §8.15 (subcontracting). Any attempt by either Party to subcontract any performance, obligation, or responsibility under this Agreement, without the prior written consent of the other Party, shall be null and void and shall constitute an event of immediate termination pursuant to §5.4 (termination for cause) of this Agreement. Each Party shall notify all of its potential subcontractors of the provisions of this §8.15 (subcontracting).

8.15.1 County Approval. If LA BioMed desires to subcontract any portion of its performance, obligations or responsibilities under this Agreement, LA BioMed shall make a written request to County for written approval to enter into the particular subcontract. County will review LA BioMed's request to subcontract and determine, in its sole discretion, whether or not to consent to such request on a case-by-case basis. County will communicate consent within reasonable time. The Director or his or her designee is hereby authorized to act for and on behalf of County pursuant to this §8.15.1 (County approval), including consenting to any subcontracting. LA BioMed's request to County shall include:

8.15.1.1 The reason(s) for the particular subcontract.

- 8.15.1.2 A detailed description of the work to be performed by the proposed subcontractor.
  - 8.15.1.3 Identification of the proposed subcontractor and an explanation of why and how the proposed subcontractor was selected.
  - 8.15.1.4 A draft copy of the proposed subcontract.
  - 8.15.1.5 Unless otherwise determined unnecessary by County, copies of certificates of insurance and performance security from the proposed subcontractor shall be provided to Hospital to ensure that the subcontractor maintains all the programs of insurance required by §2.20 (insurance coverage requirements).
  - 8.15.1.6 Any other information or certifications requested by County.
- 8.15.2 Approved Subcontracting. Notwithstanding any County consent to any subcontracting, LA BioMed shall remain responsible for any and all performance required of it under this Agreement, including the obligation to properly supervise, coordinate, and perform all work required hereunder. No subcontract shall bind or purport to bind County. Further, County approval of any subcontract shall not be construed to limit in any way LA BioMeds performance, obligations, or responsibilities to County, nor shall such approval limit any of County's rights or remedies contained in this Agreement.
- 8.15.2.1 Bound by Agreement. In the event that County consents to any subcontracting, the subcontractor, on behalf of itself, its successors and administrators, shall assume and be bound by and shall be deemed to have assumed and agreed to be bound by each and all of the provisions of this Agreement and any amendment hereto.
  - 8.15.2.2 Consent. In the event that County consents to any subcontracting, such consent shall apply to each particular subcontract only and shall not be, nor construed to be, a waiver of this §8.15.2. (consent) or a blanket consent to any further subcontracting. Hospital providing such consent does not confer Business Associate nor agency relationship between Hospital and subcontractor.
  - 8.15.2.3 Liability. LA BioMed shall be solely liable and responsible for any and all payments and other compensation to all subcontractors and their officers, employees, and agents. County shall have no liability or responsibility whatsoever for any payment or other compensation for any subcontractors or their officers, employees and agents.
  - 8.15.2.4 Copies. LA BioMed shall deliver to County a fully executed copy of each subcontract entered into by LA BioMed pursuant to this §8.15 (subcontracting), on or immediately after the effective date of

the subcontract but in no event later than the date any work is performed under the subcontract.

- 8.16 Compliance with Laws and Regulations.** All Sponsored Programs done by LA BioMed and County shall comply with all applicable Federal, State, and local laws, ordinances, rules, governmental regulations, guidelines and directives applicable to its performance hereunder, including without limitation current National Institutes of Health guidelines.
- 8.17 Governing Law; Entire Agreement.** This Agreement shall be governed by and construed in accordance with the law of the State California without reference to its choice-of-law doctrines. This Agreement, and any other documents executed in connection herewith by authorized representatives of the Parties, contain the entire agreement between the Parties relating to the subject matter contained herein, and supersede all prior or contemporaneous agreements, written or oral, with respect thereto.
- 8.18 Construction.** To the extent there are any rights, duties, obligations, or responsibilities enumerated in the recitals or otherwise in this Agreement, they shall be deemed a part of the operative provisions of this Agreement and are fully binding upon the Parties.
- 8.19 Conflict of Terms.** To the extent that there exists any conflict or inconsistency between the language of this Agreement and that of any exhibit(s), attachment(s), and any other documents incorporated herein by reference, the language found within this Agreement shall govern and prevail.
- 8.20 Conflict with Ground Lease Agreement and Master Ground Lease Agreement (MGLA),** In the event that any terms or provisions of this Agreement conflict with or are inconsistent with any of the terms and provisions of the Ground Leases No. 1, No .. 2 and No .. 3, the terms and provisions of the Ground Leases shall in all cases be deemed to control.. In the event that any terms or provisions of this Agreement conflict with or are inconsistent with any of the terms and provisions of the MGLA, the terms and provisions of the MGLA shall in all cases be deemed to control.
- 8.21 Alteration of Terms.** No addition to, or alteration of, the terms of this Agreement, whether by written or verbal understanding of the Parties, their officers, employees or agents, shall be valid and effective unless made in the form of a written amendment to this Agreement as set forth in §8.22, which is formally approved and executed by the Parties and delivered to the other Party in the same manner as this Agreement.
- 8.22 Dispute Resolution.** The Parties agree to work together to jointly resolve any perceived dispute or issue regarding a Sponsored Program Manager's activity or conduct and shall attempt to resolve any dispute arising out of or relating to this Agreement through negotiations between the representatives of both Parties or their respective designees, who have authority to settle the issue. Such informal process may be initiated, by either Party, by written notice given by the initiating Party to the other Party in accordance with the provisions set forth in §8.1 (notices). Initiating Party will provide 30 days for the other Party to cure, resolve or respond to the perceived dispute or issue, unless the Hospital determines that the Sponsored Program Manager's breach is egregious, repeated, or

persistent. Nothing herein is intended to foreclose any other rights under Agreement that each Party may have to terminate or suspend this Agreement.

8.22.1 Individual Sponsored Program Manager's breaches will be evaluated on a case-by-case basis to determine if the Sponsored Program Manager's Sponsored Program should be terminated.

8.22.2 Repeated or persistent patterns of egregious Sponsored Program Manager's breaches will result in termination of the either the Sponsored Program and/or the Sponsored Program Manger's right to conduct a Sponsored Program at the Hospital.

### **8.23 Amendments.**

8.23.1 For any change which affects the Term, payments, or any term or condition included under this Agreement, an amendment shall be prepared by County and then executed by LA BioMed and by the Governing Board or its authorized designee.

8.23.2 The Governing Board or CEO or designee may require the addition and/or change of certain terms and conditions in the Agreement during the Term, County reserves the right to add and/or change such provisions as required by the Governing Board, CEO or designee. To implement such changes, an amendment to the Agreement shall be prepared by County and then executed by LA BioMed and by the Director.

8.23.3 The reimbursement rates may be adjusted upon agreement by both Parties.

8.23.4 The Director may require, at his/her sole discretion, the addition and/or change of certain terms and conditions in the Agreement to conform to changes in federal or state law or regulation, during the Term. County reserves the unilateral right to add and/or change such provisions as required by law, regulation, without the need for LA BioMed's written consent, to preserve this Agreement's conformity and compliance to federal and state law or regulation. To implement such changes, an amendment to the Agreement shall be prepared by County and then executed by the Parties.

**8.24 Authorization Warranty.** Both Parties hereby represent and warrant that the person executing this Agreement on behalf of such Party is an authorized agent who has actual authority to bind that Party to each and every term, condition, and obligation set forth in this Agreement and that all requirements of such Party have been fulfilled to provide such actual authority.

**8.25 Fair Labor Standards.** LA BioMed shall comply with all applicable provisions of the Federal Fair Labor Standards Act and shall indemnify County for any violations of this obligation, pursuant to §7.0 (indemnification) of this Agreement.

**8.26 Employment Eligibility Verification.** Each Party warrants that it fully complies with all Federal statutes and regulations regarding employment of aliens and others, and LA

BioMed warrants that the temporary personnel which it refers to County facilities hereunder, including all independent LA BioMed personnel performing services hereunder, meet the citizenship or alien status requirements contained in Federal statutes and regulations. Each Party shall obtain, from all of its personnel performing services hereunder, all verification and other documentation of employment eligibility status required by Federal statutes and regulations as they currently exist and as they may be hereafter amended. Each Party shall retain such documentation for all such personnel for the period prescribed by law. LA BioMed shall indemnify County for any violations of this obligation, pursuant to §7.0 (indemnification) of this Agreement.

**8.27 Restrictions on Lobbying.** If any Federal monies are to be used to pay for LA BioMed's services under this Agreement, LA BioMed shall comply with all certifications and disclosure requirements prescribed by Section 319, Public Law 101-121 (31 U.S.C. § 1352) and any implementing regulations, and shall ensure that each of its subcontractors receiving funds provided under this Agreement also fully comply with all such certifications and disclosure requirements.

**8.28 County Lobbyists.** LA BioMed and each County lobbyist or County lobbying firm, as defined in County of Los Angeles Code Section 2.160.010, retained by LA BioMed, shall fully comply with the County Lobbyist Ordinance, County of Los Angeles Code Chapter 2.160. Failure on the part of LA BioMed or any County lobbyist or County lobbying firm retained by LA BioMed to fully comply with the County Lobbyist Ordinance shall constitute an event of immediate termination pursuant to §5.4 (termination for cause) of this Agreement.

**8.29 County's Child Support Compliance Program.**

8.29.1 LA BioMed's Warranty of Adherence to County's Child Support Compliance Program. LA BioMed acknowledges that County has established a goal of ensuring that all individuals who benefit financially from County through contract are in compliance with their court-ordered child, family, and spousal support obligations in order to mitigate the economic burden otherwise imposed upon County and its taxpayers. As required by County's Child Support Compliance Program (County Code Chapter 2.200) and without limiting LA BioMed's duty under this Agreement to comply with all applicable provisions of law, LA BioMed warrants that it is now in compliance and shall during the Term maintain in compliance with employment and wage reporting requirements as required by the federal Social Security Act [ (42 USC Section 653 (a) ] and California Unemployment Insurance Code Section 1088.55, and shall implement all lawfully served Wage and Earnings Withholdings Orders or Child Support Services Department (ACSSD) Notices of Wage and Earnings Assignment for Child, Family, or Spousal Support, pursuant to Code of Civil Procedure Section 706.031 and Family Code Section 5246 (b).

8.29.2 Termination for Breach of Warranty to Maintain Compliance with County's Child Support Compliance Program. Failure of LA BioMed to maintain compliance with the requirements set forth in §8.28.1 (LA BioMed's warranty

of adherence to County's child support compliance program), shall constitute an event of termination for cause pursuant to §5.4 (termination for default) under this Agreement. Without limiting the rights and remedies available to County under any other provision of this Agreement, failure of LA BioMed to cure within ninety (90) calendar days of written notice shall be grounds upon which County may terminate this contract pursuant to §5.4 (termination for default) of this Agreement and pursue debarment of LA BioMed, pursuant to County Code Chapter 2.202.

- 8.30 Merger and Integration Provision.** All exhibits, attachments and addenda to this Agreement are incorporated herein. This Agreement fully expresses all understandings of the Parties concerning all matters covered and shall constitute the entire agreement of the Parties, superseding the prior contract between the Parties regarding its subject matter. No addition to or alteration of the terms of this Agreement, whether by written or oral understanding of the Parties, their officers, agents or employees, shall be valid unless made in the form of a written amendment to this Agreement which is formally approved and executed by the Parties.
- 8.31 Severability.** If any provision of this Agreement, including all the exhibits, attachments and addenda hereto, or the application thereof to any person or circumstance, is held to be illegal or invalid, the remainder of the Agreement and the application of such provision to other persons or circumstances shall not be affected, except as otherwise provided in this §8.30 (severability). If such invalidation has the effect of materially altering the obligations of either Party, then the Parties shall diligently seek to amend the Agreement to restore the prior balance of obligations. If the Parties are unable to agree on such amendment within forty-five (45) days following notice of the invalidation, then the impaired Party may deem the invalidation an event of termination for cause under §5.4 (termination for cause), without fault of or breach by either Party.
- 8.32 Investigations.** Each Party shall cooperate regarding outside investigations of the other Party as reasonably requested by the other Party as it relates to this Agreement. If any government agency undertakes an investigation of a Party, the other Party shall comply with that Party's reasonable request to make available information and records in connection with the investigation. Compliance with this provision by either Party shall not constitute a waiver of the attorney-client privilege.
- 8.33 No Third Party Beneficiaries.** None of the provisions of this Agreement are or shall be construed as for the benefit of or enforceable by any person not a Party to this Agreement.
- 8.34 Waiver.** No waiver, express or implied, of any breach of this Agreement, shall constitute a waiver of any right under this Agreement or of any subsequent breach, whether of a similar or dissimilar nature. All of the rights or remedies permitted or available to a Party under this Agreement, or at law or in equity, shall be cumulative and not alternative, and the exercise of any right or remedy shall not constitute a waiver or election of remedies with respect to any other permitted or available right or remedy.



**8.35 Section References.** Throughout this Agreement, each section reference includes any subsection.

**8.36 Contractor Responsibility and Debarment.**

- 8.36.1 A responsible contractor is a contractor who has demonstrated the attribute of trustworthiness, as well as quality, fitness, capacity, and experience to satisfactorily perform the contract. It is County's policy to conduct business only with responsible contractors.
- 8.36.2 LA BioMed is hereby notified that, in accordance with Chapter 2.202 of the County Code, if County acquires information concerning the performance of LA BioMed on this or other agreements which indicates that LA BioMed is not responsible, County may, in addition to other remedies provided under the Agreement, debar LA BioMed from bidding or proposing on, or being awarded, and/or performing work on County agreements for a specified period of time not to exceed three (3) years, and terminate any or all existing agreements LA BioMed may have with County
- 8.36.3 County may debar LA BioMed if the Governing Board finds, in its discretion, that LA BioMed has done any of the following: (1) violated a term of an agreement with County or a nonprofit corporation created by County, (2) committed any act or omission which negatively reflects on LA BioMed's quality, fitness, or capacity to perform an agreement with County, or engaged in a pattern or practice which negatively reflects on same, (3) committed an act or offense which indicates a lack of business integrity or business honesty, or (4) made or submitted a false claim against County or any other public entity.
- 8.36.4 If there is evidence that LA BioMed may be subject to debarment, the Department will notify LA BioMed in writing of the evidence which is the basis for the proposed debarment and will advise LA BioMed of the scheduled date for a debarment hearing before County's Contractor Hearing Board.
- 8.36.5 County's Contractor Hearing Board will conduct a hearing where evidence on the proposed debarment is presented. LA BioMed shall be given an opportunity to submit evidence at that hearing. After the hearing, the Contractor Hearing Board shall prepare a tentative decision, which shall contain a recommendation regarding whether LA BioMed should be debarred, and, if so, the appropriate length of time of the debarment. LA BioMed and the Department shall be provided an opportunity to object to the tentative proposed decision prior to its presentation to the Governing Board.
- 8.36.6 After consideration of any objections, or if no objections are submitted, a record of hearing, the proposed decision, and any other recommendation of the Contractor Hearing Board shall be presented to the Governing Board. The Governing Board shall have the right to modify, deny, or adopt the proposed decision and recommendation of the Contractor Hearing Board.

8.36.7 These terms shall also apply to subcontractor(s) or Business Associates of LA BioMed.

**8.37 Use of Recycled-Content Bond Paper.** Consistent with the Governing Board's policy to reduce the amount of solid waste deposited at County landfills, LA BioMed agrees to use recycled-content paper to the maximum extent possible in connection with the services to be performed by LA BioMed under this Agreement.

**8.38 Compliance with County's Zero Tolerance Human Trafficking**

8.38.1 The Contractor acknowledges that the County has established a Zero Tolerance Human Trafficking Policy prohibiting Contractors from engaging in human trafficking.

8.38.2 If a Contractor or member of the Contractor's staff is convicted of a human trafficking offense, the County shall require that the Contractor or member of the Contractor's staff be removed immediately from performing services under this Agreement. The County will not be under any obligation to disclose confidential information regarding the offenses other than those required by law.

8.38.3 Disqualification of any member of the Contractor's staff pursuant to this Sub-paragraph shall not relieve the Contractor of its obligation to complete all work in accordance with the terms and conditions of this Agreement."

**8.39 Compliance with Jury Service Program.**

8.39.1 Jury Service Program. This Agreement is subject to the provisions of the County's ordinance entitled Contractor Employee Jury Service ("Jury Service Program") as codified in Sections 2.203.010 through 2.203.090 of the County Code.

8.39.2 Written Employee Jury Service Policy:

8.39.2.1 Unless LA BioMed has demonstrated to County's satisfaction either that LA BioMed is not a "contractor" as defined under the Jury Service Program (Section 2.203.020 of the County Code) or that LA BioMed qualifies for an exception to the Jury Service Program (Section 2.203.070 of the County Code), LA BioMed shall have and adhere to a written policy that provides that its employees shall receive from LA BioMed, on an annual basis, no less than five (5) days of regular pay for actual jury service served. LA BioMed's policy may further provide that employees deposit any fees received for such jury service with LA BioMed or that LA BioMed deduct from the employee's regular pay the fee received for jury service.

8.39.2.2 For purpose of this Section, and as set forth in the Jury Service Program provision of the County Code as described hereinabove: "contractor" shall mean a person, partnership, corporation, or other entity, that has a contract with County, or a subcontract with a County contractor, and has received, or will receive, an aggregate sum of Fifty Thousand Dollars (\$50,000) or more in any twelve (12) month period under one (1) or more County contracts or subcontracts; "employee" shall mean any California resident who is a full-time employee of LA BioMed; and "full-time" shall mean forty (40) hours or more worked per week, or a lesser number of hours, if: a) the lesser number is a recognized industry standard as determined by County, or b) LA BioMed has a long-standing practice that defines the lesser number of hours as full-time. Full-time employees providing short-term temporary services of ninety (90) days or less within a twelve (12) month period are not considered full-time for purposes of the Jury Service Program. If LA BioMed uses any subcontractor to perform services for County under this Agreement, the subcontractor shall also be subject to the provisions of this Section. The provisions of this Section shall be inserted into any such subcontract agreement and a copy of the Jury Service Program shall be attached to such subcontract agreement.

8.39.2.3 If LA BioMed is not required to comply with the Jury Service Program on the Effective Date of this Agreement, LA BioMed shall have a continuing obligation to review the applicability of its "exception status" from the Jury Service Program, and LA BioMed shall immediately notify County if LA BioMed at any time either comes within the Jury Service Program's definitions of "contractor", or if LA BioMed no longer qualifies for an exception to the Jury Service Program. In either event, LA BioMed shall immediately implement a written policy consistent with the Jury Service Program. County may also require, at any time during the Term, and at its sole discretion, that LA BioMed demonstrate to County's satisfaction that LA BioMed either continues to remain outside of the Jury Service Program's definition of "contractor" and/or that LA BioMed continues to qualify for an exception to the Jury Service Program. LA BioMed and its subcontractors, if applicable, may demonstrate their exemption, or compliance, with the above subject Jury Service Program by completing a "County of Los Angeles Contractor Employee Jury Service Program Application for Exemption and Certification Form" which should be obtained from, and returned to, the Director within ten (10) calendar days before the Effective Date of this Agreement.

8.39.2.4 LA BioMed's violation of this Section of the Agreement may constitute a material breach of this Agreement. In the event of such breach, County may, in its sole discretion, terminate this Agreement

and/or bar LA BioMed from the award of future County contracts for a period of time consistent with the seriousness of the breach.

- 8.40 Notice to Employees Regarding the Safely Surrendered Baby Law.** LA BioMed shall notify and provide to its employees, and shall require each subcontractor to notify and provide to its employees, a fact sheet regarding the Safely Surrendered Baby Law, its implementation in Los Angeles County, and where and how to safely surrender a baby. The fact sheet is set forth in English and Spanish and is also available on the Internet at [www.babysafela.org](http://www.babysafela.org) for printing purposes."
- 8.41 LA BioMed's Acknowledgment of County's Commitment to the Safely Surrendered Baby Law.** LA BioMed acknowledges that County places a high priority on the implementation of the Safely Surrendered Baby Law. LA BioMed understands that it is the County's policy to encourage all County contractors to voluntarily post County's "Safely Surrendered Baby Law" poster in a prominent position at LA BioMed's place of business. LA BioMed will also encourage its subcontractors, if any, to post this poster in a prominent position in the subcontractor's place of business. County's Department of Children and Family Services will supply LA BioMed with the poster to be used."
- 8.42 LA BioMed's Warranty of Compliance with County's Defaulted Property Tax Reduction Program.**
- 8.42.1 LA BioMed acknowledges that County has established a goal of ensuring that all individuals and businesses that benefit financially from County through contract are current in paying their property tax obligations (secured and unsecured roll) in order to mitigate the economic burden otherwise imposed upon County and its taxpayers.
- 8.42.2 Unless LA BioMed qualifies for an exemption or exclusion, LA BioMed warrants and certifies that to the best of its knowledge it is now in compliance, and during the Term will maintain compliance, with Los Angeles Code Chapter 2.206.
- 8.43 Time Off for Voting.** LA BioMed shall notify its employees, and shall require each subcontractor to notify and provide to its employees, information regarding the time off for voting law (Elections Code Section 14000). Not less than ten (10) days before every statewide election, LA BioMed and its subcontractors shall keep posted conspicuously at the place of work, if practicable, or elsewhere where it can be seen as employees come or go to their place of work, a notice setting forth the provisions of Section 14000.
- 8.44 Use of Name and Trademarks.** Except as required by law or permitted by this Agreement, neither Party shall use the name, logo, trademark, or symbol of the other Party or its affiliates in any advertising or promotional material without the prior written consent of the other Party.
- 8.45 Compliance with the County Policy of Equity.** LA BioMed acknowledges that the County takes its commitment to preserving the dignity and professionalism of the workplace very seriously, as set forth in the County Policy of Equity (CPOE) (<https://ceop.bos.lacounty.gov/pdf/PolicyOfEquity.pdf>). The Contractor further

acknowledges that the County strives to provide a workplace free from discrimination, harassment, retaliation and inappropriate conduct based on a protected characteristic, and which may violate the CPOE. The Contractor, its employees and subcontractors acknowledge and certify receipt and understanding of the CPOE. Failure of the Contractor, its employees or its subcontractors to uphold the County's expectations of a workplace free from harassment and discrimination, including inappropriate conduct based on a protected characteristic, may subject the Contractor to termination of contractual agreements as well as civil liability.

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IN WITNESS WHEREOF, Governing Board has caused this Agreement to be executed by the Director and LA BioMed has caused this Agreement to be executed on its behalf by its duly authorized officer, as of the Effective Date.

COUNTY OF LOS ANGELES

By: \_\_\_\_\_  
Christina R. Ghaly, M.D.  
Director of Health Services

THE LOS ANGELES BIOMEDICAL RESEARCH  
INSTITUTE AT HARBOR-UCLA MEDICAL  
CENTER

By: \_\_\_\_\_  
Signature

\_\_\_\_\_  
David Meyer, Ph.D.

\_\_\_\_\_  
LA BioMed CEO

APPROVED AS TO FORM:

MARY C. WICKHAM  
County Counsel

By \_\_\_\_\_  
Caroline S. Craddock, Deputy County Counsel

**EXHIBIT I**

**FRAMEWORK FOR RESEARCH PROJECT CATEGORIZATION/DHS RESOURCE SUPPORT & BILLING RATES**

<p><b>Framework for research project categorization and DHS resource support (Each Sponsored Program to be reviewed by Hospital and/or DHS on a case-by-case basis)</b></p>	<p>DHS Services or Supplies (a)</p>	<p>DHS Staff time and effort (b)</p>		<p>Access to Patients for study recruitment (study performed at another institution)</p>
<p>Category 1: (c)</p> <p>Research performed at DHS sites and well aligned with DHS business needs and strategic priorities. It is anticipated that the results of the research will have significant direct impact on clinical operations for a significant number of DHS patients. Direct DHS resources can be used to fully support projects in this category; however, researchers should make every effort to obtain extramural funding.</p>	<p>DHS supports fully or partially</p>	<p>DHS supports fully or partially</p>		<p>DHS supports fully or partially</p>

<b>Framework for research project categorization and DHS resource support (Each Sponsored Program to be reviewed by Hospital and/or DHS on a case-by-case basis)</b>	DHS Services or Supplies (a)	DHS Staff time and effort (b)		Access to Patients for study recruitment (study performed at another institution)
<p>Category 2:</p> <p>Research performed at DHS sites and well aligned with DHS business needs and strategic priorities. The research results are expected to affect care of the population served by DHS. Some external funding support is required to accomplish the research objectives</p>	DHS supports partially or none	DHS supports partially or none		<p>DHS supports partially or none for group recruitment.</p> <p>Individual patient referral to an appropriate study is always allowed</p>
<p>Category 3:</p> <p>Research performed at DHS sites with potential benefit to DHS patients in the future. DHS will allow access to resources, but the study must cover the cost of these resources.</p>	<p>DHS supports</p> <p>Study must fully fund at least variable cost (d)</p>	<p>DHS supports</p> <p>Study must fully fund at least variable cost (d)</p>		<p>DHS allows access, but study must cover cost of any negative operational impact of recruitment</p> <p>Individual patient referral to an appropriate study is always allowed</p>



<b>Framework for research project categorization and DHS resource support (Each Sponsored Program to be reviewed by Hospital and/or DHS on a case-by-case basis)</b>	DHS Services or Supplies (a)	DHS Staff time and effort (b)		Access to Patients for study recruitment (study performed at another institution)
<p>Category 4:</p> <p>Research intended to support the development of new drugs, medical devices, or procedures that, although having the potential of improving the care of patients in the future, does not address a key component of DHS's service priorities or needs that disproportionately affect DHS's patient population.</p> <p>These projects have potential positive impact for the DHS population (e.g. drug discovery)</p>	Full compensation of at least variable costs (d)	Full compensation of at least variable l costs (d)		<p>DHS allows access, but study must cover cost of any negative operational impact of recruitment</p> <p>Individual patient referral to an appropriate study is always allowed</p>
<p>Category 5:</p> <p>Research that has no benefit to DHS or its partners and should not be conducted on a DHS campus</p>	No	No		No

- (a) DHS Services and supplies includes clinical services and supplies. This excludes outpatient pharmaceuticals (340b). Subject to the facility CEO's approval, drugs may be issued from the inpatient pharmacy inventory at average wholesale prices.
- (b) DHS staff time and effort includes administrative and clinical staff. DHS staff time will be based upon actual hourly salary, plus variable employee benefits. Space and related space support (utilities) is subject to availability and approval by the facility's Chief Executive Officer. Space and related space support will be billed based upon County CEO Real Estate's fair market value rental rate per square foot and facility's utilities cost per square foot, absent other research master space lease agreement provisions set forth in the Master Ground Lease Agreement between the parties. .
- (c) Research performed at DHS sites and well-aligned with DHS business needs and strategic priorities. It is anticipated that the results of the research will have significant direct impact on clinical operations for a significant number of DHS patients. Direct DHS resources can be used to fully support projects in this category; however, researchers should make every effort to obtain extramural funding. This research category does not include patient care or any clinical trials.
- (d) For purposes of determining variable costs, the following rate structure is applicable. Rates billed will be based upon date of service.
- Inpatient services: Medi-Cal daily per diem rate.
  - Outpatient services: Medicare fee schedule + 20%.
  - Ancillary services: Medicare fee schedule +20%.
  - Information Technology services. Total cost is the number of work hours multiplied by non-LA BioMed Programmer's actual hourly rate plus variable employee benefits.

## EXHIBIT II

### **BUSINESS ASSOCIATE AGREEMENT UNDER THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996 ("HIPAA")**

County is a Covered Entity as defined by, and subject to the requirements and prohibitions of, the Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191 ("HIPAA"), and regulations promulgated thereunder, including the Privacy, Security, Breach Notification, and Enforcement Rules at 45 Code of Federal Regulations (C.F.R.) Parts 160 and 164 (collectively, the "HIPAA Rules").

Contractor performs or provides functions, activities or services to County that require Contractor in order to provide such functions, activities or services to create, access, receive, maintain, and/or transmit information that includes or that may include Protected Health Information, as defined by the HIPAA Rules. As such, Contractor is a Business Associate, as defined by the HIPAA Rules, and is therefore subject to those provisions of the HIPAA Rules that are applicable to Business Associates.

The HIPAA Rules require a written agreement ("Business Associate Agreement") between County and Contractor in order to mandate certain protections for the privacy and security of Protected Health Information, and these HIPAA Rules prohibit the disclosure to or use of Protected Health Information by Contractor if such an agreement is not in place.

This Business Associate Agreement and its provisions are intended to protect the privacy and provide for the security of Protected Health Information disclosed to or used by Contractor in compliance with the HIPAA Rules.

Therefore, the parties agree as follows:

#### **1.0 DEFINITIONS**

- 1.1 "Breach" has the same meaning as the term "breach" at 45 C.F.R. § 164.402.
- 1.2 "Business Associate" has the same meaning as the term "business associate" at 45 C.F.R. § 160.103. For the convenience of the parties, a "business associate" is a person or entity, other than a member of the workforce of covered entity, who performs functions or activities on behalf of, or provides certain services to, a covered entity that involve access by the business associate to Protected Health Information. A "business associate" also is a subcontractor that creates, receives, maintains, or transmits Protected Health Information on behalf of another business associate. And in reference to the party to this Business Associate Agreement "Business Associate" shall mean Contractor.
- 1.3 "Covered Entity" has the same meaning as the term "covered entity" at 45 C.F.R. § 160.103, and in reference to the party to this Business Associate Agreement, "Covered Entity" shall mean County.

- 1.4 "Data Aggregation" has the same meaning as the term "data aggregation" at 45 C.F.R. § 164.501.
- 1.5 "De-identification" refers to the de-identification standard at 45 C.F.R. § 164.514.
- 1.6 "Designated Record Set" has the same meaning as the term "designated record set" at 45 C.F.R. § 164.501.
- 1.7 "Disclose" and "Disclosure" mean, with respect to Protected Health Information, the release, transfer, provision of access to, or divulging in any other manner of Protected Health Information outside Business Associate's internal operations or to other than its workforce. (See 45 C.F.R. § 160.103.)
- 1.8 "Electronic Health Record" means an electronic record of health-related information on an individual that is created, gathered, managed, and consulted by authorized health care clinicians and staff. (See 42 U.S. C. § 17921.)
- 1.9 "Electronic Media" has the same meaning as the term "electronic media" at 45 C.F.R. § 160.103. For the convenience of the parties, electronic media means (1) Electronic storage material on which data is or may be recorded electronically, including, for example, devices in computers (hard drives) and any removable/transportable digital memory medium, such as magnetic tape or disk, optical disk, or digital memory card; (2) Transmission media used to exchange information already in electronic storage media. Transmission media include, for example, the Internet, extranet or intranet, leased lines, dial-up lines, private networks, and the physical movement of removable/transportable electronic storage media. Certain transmissions, including of paper, via facsimile, and of voice, via telephone, are not considered to be transmissions via electronic media if the information being exchanged did not exist in electronic form immediately before the transmission.
- 1.10 "Electronic Protected Health Information" has the same meaning as the term "electronic protected health information" at 45 C.F.R. § 160.103, limited to Protected Health Information created or received by Business Associate from or on behalf of Covered Entity. For the convenience of the parties, Electronic Protected Health Information means Protected Health Information that is (i) transmitted by electronic media; (ii) maintained in electronic media.
- 1.11 "Health Care Operations" has the same meaning as the term "health care operations" at 45 C.F.R. § 164.501.
- 1.12 "Individual" has the same meaning as the term "individual" at 45 C.F.R. § 160.103. For the convenience of the parties, Individual means the person who is the subject of Protected Health Information and shall include a person who qualifies as a personal representative in accordance with 45 C.F.R. § 164.502 (g).
- 1.13 "Law Enforcement Official" has the same meaning as the term "law enforcement official" at 45 C.F.R. § 164.103.

- 1.14 "Minimum Necessary" refers to the minimum necessary standard at 45 C.F.R. § 164.502 (b).
- 1.15 "Protected Health Information" has the same meaning as the term "protected health information" at 45 C.F.R. § 160.103, limited to the information created or received by Business Associate from or on behalf of Covered Entity. For the convenience of the parties, Protected Health Information includes information that (i) relates to the past, present or future physical or mental health or condition of an Individual; the provision of health care to an Individual, or the past, present or future payment for the provision of health care to an Individual; (ii) identifies the Individual (or for which there is a reasonable basis for believing that the information can be used to identify the Individual); and (iii) is created, received, maintained, or transmitted by Business Associate from or on behalf of Covered Entity, and includes Protected Health Information that is made accessible to Business Associate by Covered Entity. "Protected Health Information" includes Electronic Protected Health Information.
- 1.16 "Required by Law" " has the same meaning as the term "required by law" at 45 C.F.R. § 164.103.
- 1.17 "Secretary" has the same meaning as the term "secretary" at 45 C.F.R. § 160.103
- 1.18 "Security Incident" has the same meaning as the term "security incident" at 45 C.F.R. § 164.304.
- 1.19 "Services" means, unless otherwise specified, those functions, activities, or services in the applicable underlying Agreement, Contract, Master Agreement, Work Order, or Purchase Order or other service arrangement, with or without payment, that gives rise to Contractor's status as a Business Associate.
- 1.20 "Subcontractor" has the same meaning as the term "subcontractor" at 45 C.F.R. § 160.103.
- 1.21 "Unsecured Protected Health Information" has the same meaning as the term "unsecured protected health information" at 45 C.F.R. § 164.402.
- 1.22 "Use" or "Uses" means, with respect to Protected Health Information, the sharing, employment, application, utilization, examination or analysis of such Information within Business Associate's internal operations. (See 45 C.F.R § 164.103.)
- 1.23 Terms used, but not otherwise defined in this Business Associate Agreement, have the same meaning as those terms in the HIPAA Rules.

## **2.0 PERMITTED AND REQUIRED USES AND DISCLOSURES OF PROTECTED HEALTH INFORMATION**

- 2.1 Business Associate may only Use and/or Disclose Protected Health Information as necessary to perform Services, and/or as necessary to comply with the obligations of this Business Associate Agreement.
- 2.2 Business Associate may Use Protected Health Information for de-identification of the information if de-identification of the information is required to provide Services.
- 2.3 Business Associate may Use or Disclose Protected Health Information as Required by Law.
- 2.4 Business Associate shall make Uses and Disclosures and requests for Protected Health Information consistent with the Covered Entity's applicable Minimum Necessary policies and procedures.
- 2.5 Business Associate may Use Protected Health Information as necessary for the proper management and administration of its business or to carry out its legal responsibilities.
- 2.6 Business Associate may Disclose Protected Health Information as necessary for the proper management and administration of its business or to carry out its legal responsibilities, provided the Disclosure is Required by Law or Business Associate obtains reasonable assurances from the person to whom the Protected Health Information is disclosed (i.e., the recipient) that it will be held confidentially and Used or further Disclosed only as Required by Law or for the purposes for which it was disclosed to the recipient and the recipient notifies Business Associate of any instances of which it is aware in which the confidentiality of the Protected Health Information has been breached.
- 2.7 Business Associate may provide Data Aggregation services relating to Covered Entity's Health Care Operations if such Data Aggregation services are necessary in order to provide Services.

## **3.0 PROHIBITED USES AND DISCLOSURES OF PROTECTED HEALTH INFORMATION**

- 3.1 Business Associate shall not Use or Disclose Protected Health Information other than as permitted or required by this Business Associate Agreement or as Required by Law.
- 3.2 Business Associate shall not Use or Disclose Protected Health Information in a manner that would violate Subpart E of 45 C.F.R. Part 164 if done by Covered Entity, except for the specific Uses and Disclosures set forth in Sections 2.5 and 2.6.

- 3.3 Business Associate shall not Use or Disclose Protected Health Information for de-identification of the information except as set forth in section 2.2.

#### **4.0 OBLIGATIONS TO SAFEGUARD PROTECTED HEALTH INFORMATION**

- 4.1 Business Associate shall implement, use, and maintain appropriate safeguards to prevent the Use or Disclosure of Protected Health Information other than as provided for by this Business Associate Agreement.
- 4.2 Business Associate shall comply with Subpart C of 45 C.F.R Part 164 with respect to Electronic Protected Health Information, to prevent the Use or Disclosure of such information other than as provided for by this Business Associate Agreement.

#### **5.0 REPORTING NON-PERMITTED USES OR DISCLOSURES, SECURITY INCIDENTS, AND BREACHES OF UNSECURED PROTECTED HEALTH INFORMATION**

- 5.1 Business Associate shall report to Covered Entity any Use or Disclosure of Protected Health Information not permitted by this Business Associate Agreement, any Security Incident, and/ or any Breach of Unsecured Protected Health Information as further described in Sections 5.1.1, 5.1.2, and 5.1.3.
- 5.1.1 Business Associate shall report to Covered Entity any Use or Disclosure of Protected Health Information by Business Associate, its employees, representatives, agents or Subcontractors not provided for by this Agreement of which Business Associate becomes aware.
- 5.1.2 Business Associate shall report to Covered Entity any Security Incident of which Business Associate becomes aware.
- 5.1.3 Business Associate shall report to Covered Entity any Breach by Business Associate, its employees, representatives, agents, workforce members, or Subcontractors of Unsecured Protected Health Information that is known to Business Associate or, by exercising reasonable diligence, would have been known to Business Associate. Business Associate shall be deemed to have knowledge of a Breach of Unsecured Protected Health Information if the Breach is known, or by exercising reasonable diligence would have been known, to any person, other than the person committing the Breach, who is an employee, officer, or other agent of Business Associate, including a Subcontractor, as determined in accordance with the federal common law of agency.
- 5.2 Except as provided in Section 5.3, for any reporting required by Section 5.1, Business Associate shall provide, to the extent available, all information required by, and within the times frames specified in, Sections 5.2.1 and 5.2.2.
- 5.2.1 Business Associate shall make an immediate telephonic report upon discovery of the non-permitted Use or Disclosure of Protected Health

Information, Security Incident or Breach of Unsecured Protected Health Information to **(562) 940-3335** that minimally includes:

- (a) A brief description of what happened, including the date of the non-permitted Use or Disclosure, Security Incident, or Breach and the date of Discovery of the non-permitted Use or Disclosure, Security Incident, or Breach, if known;
- (b) The number of Individuals whose Protected Health Information is involved;
- (c) A description of the specific type of Protected Health Information involved in the non-permitted Use or Disclosure, Security Incident, or Breach (such as whether full name, social security number, date of birth, home address, account number, diagnosis, disability code or other types of information were involved);
- (d) The name and contact information for a person highly knowledgeable of the facts and circumstances of the non-permitted Use or Disclosure of PHI, Security Incident, or Breach

5.2.2 Business Associate shall make a written report without unreasonable delay and in no event later than three (3) business days from the date of discovery by Business Associate of the non-permitted Use or Disclosure of Protected Health Information, Security Incident, or Breach of Unsecured Protected Health Information and to the Chief HIPAA Privacy Officer at: Chief HIPAA Privacy Officer, Kenneth Hahn Hall of Administration, 500 West Temple Street, Suite 525, Los Angeles, California 90012, [HIPAA@auditor.lacounty.gov](mailto:HIPAA@auditor.lacounty.gov), that includes, to the extent possible:

- (a) A brief description of what happened, including the date of the non-permitted Use or Disclosure, Security Incident, or Breach and the date of Discovery of the non-permitted Use or Disclosure, Security Incident, or Breach, if known;
- (b) The number of Individuals whose Protected Health Information is involved;
- (c) A description of the specific type of Protected Health Information involved in the non-permitted Use or Disclosure, Security Incident, or Breach (such as whether full name, social security number, date of birth, home address, account number, diagnosis, disability code or other types of information were involved);
- (d) The identification of each Individual whose Unsecured Protected Health Information has been, or is reasonably believed by Business Associate to have been, accessed, acquired, Used, or Disclosed;



- (e) Any other information necessary to conduct an assessment of whether notification to the Individual(s) under 45 C.F.R. § 164.404 is required;
- (f) Any steps Business Associate believes that the Individual(s) could take to protect him or herself from potential harm from the non-permitted Use or Disclosure, Security Incident, or Breach;
- (g) A brief description of what Business Associate is doing to investigate, to mitigate harm to the Individual(s), and to protect against any further similar occurrences; and
- (h) The name and contact information for a person highly knowledgeable of the facts and circumstances of the non-permitted Use or Disclosure of PHI, Security Incident, or Breach.

5.2.3 If Business Associate is not able to provide the information specified in Section 5.2.1 or 5.2.2 at the time of the required report, Business Associate shall provide such information promptly thereafter as such information becomes available.

5.3 Business Associate may delay the notification required by Section 5.1.3, if a law enforcement official states to Business Associate that notification would impede a criminal investigation or cause damage to national security.

5.3.1 If the law enforcement official's statement is in writing and specifies the time for which a delay is required, Business Associate shall delay its reporting and/or notification obligation(s) for the time period specified by the official.

5.3.2 If the statement is made orally, Business Associate shall document the statement, including the identity of the official making the statement, and delay its reporting and/or notification obligation(s) temporarily and no longer than 30 days from the date of the oral statement, unless a written statement as described in Section 5.3.1 is submitted during that time.

## **6.0 WRITTEN ASSURANCES OF SUBCONTRACTORS**

6.1 In accordance with 45 C.F.R. § 164.502 (e)(1)(ii) and § 164.308 (b)(2), if applicable, Business Associate shall ensure that any Subcontractor that creates, receives, maintains, or transmits Protected Health Information on behalf of Business Associate is made aware of its status as a Business Associate with respect to such information and that Subcontractor agrees in writing to the same restrictions, conditions, and requirements that apply to Business Associate with respect to such information.

6.2 Business Associate shall take reasonable steps to cure any material breach or violation by Subcontractor of the agreement required by Section 6.1.

- 6.3 If the steps required by Section 6.2 do not cure the breach or end the violation, Contractor shall terminate, if feasible, any arrangement with Subcontractor by which Subcontractor creates, receives, maintains, or transmits Protected Health Information on behalf of Business Associate.
- 6.4 If neither cure nor termination as set forth in Sections 6.2 and 6.3 is feasible, Business Associate shall immediately notify County.
- 6.5 Without limiting the requirements of Section 6.1, the agreement required by Section 6.1 (Subcontractor Business Associate Agreement) shall require Subcontractor to contemporaneously notify Covered Entity in the event of a Breach of Unsecured Protected Health Information.
- 6.6 Without limiting the requirements of Section 6.1, agreement required by Section 6.1 (Subcontractor Business Associate Agreement) shall include a provision requiring Subcontractor to destroy, or in the alternative to return to Business Associate, any Protected Health Information created, received, maintained, or transmitted by Subcontractor on behalf of Business Associate so as to enable Business Associate to comply with the provisions of Section 18.4.
- 6.7 Business Associate shall provide to Covered Entity, at Covered Entity's request, a copy of any and all Subcontractor Business Associate Agreements required by Section 6.1.
- 6.8 Sections 6.1 and 6.7 are not intended by the parties to limit in any way the scope of Business Associate's obligations related to Subcontracts or Subcontracting in the applicable underlying Agreement, Contract, Master Agreement, Work Order, Purchase Order, or other services arrangement, with or without payment, that gives rise to Contractor's status as a Business Associate.

## **7.0 ACCESS TO PROTECTED HEALTH INFORMATION**

- 7.1 To the extent Covered Entity determines that Protected Health Information is maintained by Business Associate or its agents or Subcontractors in a Designated Record Set, Business Associate shall, within two (2) business days after receipt of a request from Covered Entity, make the Protected Health Information specified by Covered Entity available to the Individual(s) identified by Covered Entity as being entitled to access and shall provide such Individual(s) or other person(s) designated by Covered Entity with a copy the specified Protected Health Information, in order for Covered Entity to meet the requirements of 45 C.F.R. § 164.524.
- 7.2 If any Individual requests access to Protected Health Information directly from Business Associate or its agents or Subcontractors, Business Associate shall notify Covered Entity in writing within two (2) days of the receipt of the request. Whether access shall be provided or denied shall be determined by Covered Entity.

- 7.3 To the extent that Business Associate maintains Protected Health Information that is subject to access as set forth above in one or more Designated Record Sets electronically and if the Individual requests an electronic copy of such information, Business Associate shall provide the Individual with access to the Protected Health Information in the electronic form and format requested by the Individual, if it is readily producible in such form and format; or, if not, in a readable electronic form and format as agreed to by Covered Entity and the Individual.

## **8.0 AMENDMENT OF PROTECTED HEALTH INFORMATION**

- 8.1 To the extent Covered Entity determines that any Protected Health Information is maintained by Business Associate or its agents or Subcontractors in a Designated Record Set, Business Associate shall, within ten (10) business days after receipt of a written request from Covered Entity, make any amendments to such Protected Health Information that are requested by Covered Entity, in order for Covered Entity to meet the requirements of 45 C.F.R. § 164.526.
- 8.2 If any Individual requests an amendment to Protected Health Information directly from Business Associate or its agents or Subcontractors, Business Associate shall notify Covered Entity in writing within five (5) days of the receipt of the request. Whether an amendment shall be granted or denied shall be determined by Covered Entity.

## **9.0 ACCOUNTING OF DISCLOSURES OF PROTECTED HEALTH INFORMATION**

- 9.1 Business Associate shall maintain an accounting of each Disclosure of Protected Health Information made by Business Associate or its employees, agents, representatives or Subcontractors, as is determined by Covered Entity to be necessary in order to permit Covered Entity to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance with 45 C.F.R. § 164.528.
- 9.1.1 Any accounting of disclosures provided by Business Associate under Section 9.1 shall include:
- (a) The date of the Disclosure;
  - (b) The name, and address if known, of the entity or person who received the Protected Health Information;
  - (c) A brief description of the Protected Health Information Disclosed; and
  - (d) A brief statement of the purpose of the Disclosure.
- 9.1.2 For each Disclosure that could require an accounting under Section 9.1, Business Associate shall document the information specified in Section

9.1.1, and shall maintain the information for six (6) years from the date of the Disclosure.

9.2 Business Associate shall provide to Covered Entity, within ten (10) business days after receipt of a written request from Covered Entity, information collected in accordance with Section 9.1.1 to permit Covered Entity to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance with 45 C.F.R. § 164.528.

9.3 If any Individual requests an accounting of disclosures directly from Business Associate or its agents or Subcontractors, Business Associate shall notify Covered Entity in writing within five (5) days of the receipt of the request, and shall provide the requested accounting of disclosures to the Individual(s) within 30 days. The information provided in the accounting shall be in accordance with 45 C.F.R. § 164.528.

## **10.0 COMPLIANCE WITH APPLICABLE HIPAA RULES**

10.1 To the extent Business Associate is to carry out one or more of Covered Entity's obligation(s) under Subpart E of 45 C.F.R. Part 164, Business Associate shall comply with the requirements of Subpart E that apply to Covered Entity's performance of such obligation(s).

10.2 Business Associate shall comply with all HIPAA Rules applicable to Business Associate in the performance of Services.

## **11.0 AVAILABILITY OF RECORDS**

11.1 Business Associate shall make its internal practices, books, and records relating to the Use and Disclosure of Protected Health Information received from, or created or received by Business Associate on behalf of Covered Entity available to the Secretary for purposes of determining Covered Entity's compliance with the Privacy and Security Regulations.

11.2 Unless prohibited by the Secretary, Business Associate shall immediately notify Covered Entity of any requests made by the Secretary and provide Covered Entity with copies of any documents produced in response to such request.

## **12.0 MITIGATION OF HARMFUL EFFECTS**

12.1 Business Associate shall mitigate, to the extent practicable, any harmful effect of a Use or Disclosure of Protected Health Information by Business Associate in violation of the requirements of this Business Associate Agreement that is known to Business Associate.

## **13.0 BREACH NOTIFICATION TO INDIVIDUALS**

- 13.1 Business Associate shall, to the extent Covered Entity determines that there has been a Breach of Unsecured Protected Health Information by Business Associate, its employees, representatives, agents or Subcontractors, provide breach notification to the Individual in a manner that permits Covered Entity to comply with its obligations under 45 C.F.R. § 164.404.
- 13.1.1 Business Associate shall notify, subject to the review and approval of Covered Entity, each Individual whose Unsecured Protected Health Information has been, or is reasonably believed to have been, accessed, acquired, Used, or Disclosed as a result of any such Breach.
- 13.1.2 The notification provided by Business Associate shall be written in plain language, shall be subject to review and approval by Covered Entity, and shall include, to the extent possible:
- (a) A brief description of what happened, including the date of the Breach and the date of the Discovery of the Breach, if known;
  - (b) A description of the types of Unsecured Protected Health Information that were involved in the Breach (such as whether full name, social security number, date of birth, home address, account number, diagnosis, disability code, or other types of information were involved);
  - (c) Any steps the Individual should take to protect him or herself from potential harm resulting from the Breach;
  - (d) A brief description of what Business Associate is doing to investigate the Breach, to mitigate harm to Individual(s), and to protect against any further Breaches; and
  - (e) Contact procedures for Individual(s) to ask questions or learn additional information, which shall include a toll-free telephone number, an e-mail address, Web site, or postal address.
- 13.2 Covered Entity, in its sole discretion, may elect to provide the notification required by Section 13.1 and/or to establish the contact procedures described in Section 13.1.2.
- 13.3 Business Associate shall reimburse Covered Entity any and all costs incurred by Covered Entity, in complying with Subpart D of 45 C.F.R. Part 164, including but not limited to costs of notification, internet posting, or media publication, as a result of Business Associate's Breach of Unsecured Protected Health Information; Covered Entity shall not be responsible for any costs incurred by Business Associate in providing the notification required by 13.1 or in establishing the contact procedures required by Section 13.1.2.

#### **14.0 INDEMNIFICATION**

- 14.1 Business Associate shall indemnify, defend, and hold harmless Covered Entity, its Special Districts, elected and appointed officers, employees, and agents from and against any and all liability, including but not limited to demands, claims, actions, fees, costs, expenses (including attorney and expert witness fees), and penalties and/or fines (including regulatory penalties and/or fines), arising from or connected with Business Associate's acts and/or omissions arising from and/or relating to this Business Associate Agreement, including, but not limited to, compliance and/or enforcement actions and/or activities, whether formal or informal, by the Secretary or by the Attorney General of the State of California.
- 14.2 Section 14.1 is not intended by the parties to limit in any way the scope of Business Associate's obligations related to Insurance and/or Indemnification in the applicable underlying Agreement, Contract, Master Agreement, Work Order, Purchase Order, or other services arrangement, with or without payment, that gives rise to Contractor's status as a Business Associate.

#### **15.0 OBLIGATIONS OF COVERED ENTITY**

- 15.1 Covered Entity shall notify Business Associate of any current or future restrictions or limitations on the Use or Disclosure of Protected Health Information that would affect Business Associate's performance of the Services, and Business Associate shall thereafter restrict or limit its own Uses and Disclosures accordingly.
- 15.2 Covered Entity shall not request Business Associate to Use or Disclose Protected Health Information in any manner that would not be permissible under Subpart E of 45 C.F.R. Part 164 if done by Covered Entity, except to the extent that Business Associate may Use or Disclose Protected Health Information as provided in Sections 2.3, 2.5, and 2.6.

#### **16.0 TERM**

- 16.1 Unless sooner terminated as set forth in Section 17, the term of this Business Associate Agreement shall be the same as the term of the applicable underlying Agreement, Contract, Master Agreement, Work Order, Purchase Order, or other service arrangement, with or without payment, that gives rise to Contractor's status as a Business Associate.
- 16.2 Notwithstanding Section 16.1, Business Associate's obligations under Sections 11, 14, and 18 shall survive the termination or expiration of this Business Associate Agreement.

#### **17.0 TERMINATION FOR CAUSE**

- 17.1 In addition to and notwithstanding the termination provisions set forth in the applicable underlying Agreement, Contract, Master Agreement, Work Order, Purchase Order, or other services arrangement, with or without payment, that gives

rise to Contractor's status as a Business Associate, if either party determines that the other party has violated a material term of this Business Associate Agreement, and the breaching party has not cured the breach or ended the violation within the time specified by the non-breaching party, which shall be reasonable given the nature of the breach and/or violation, the non-breaching party may terminate this Business Associate Agreement.

- 17.2 In addition to and notwithstanding the termination provisions set forth in the applicable underlying Agreement, Contract, Master Agreement, Work Order, Purchase Order, or other services arrangement, with or without payment, that gives rise to Contractor's status as a Business Associate, if either party determines that the other party has violated a material term of this Business Associate Agreement, and cure is not feasible, the non-breaching party may terminate this Business Associate Agreement immediately.

## **18.0 DISPOSITION OF PROTECTED HEALTH INFORMATION UPON TERMINATION OR EXPIRATION**

- 18.1 Except as provided in Section 18.3, upon termination for any reason or expiration of this Business Associate Agreement, Business Associate shall return or, if agreed to by Covered entity, shall destroy as provided for in Section 18.2, all Protected Health Information received from Covered Entity, or created, maintained, or received by Business Associate on behalf of Covered Entity, that Business Associate, including any Subcontractor, still maintains in any form. Business Associate shall retain no copies of the Protected Health Information.
- 18.2 Destruction for purposes of Section 18.2 and Section 6.6 shall mean that media on which the Protected Health Information is stored or recorded has been destroyed and/or electronic media have been cleared, purged, or destroyed in accordance with the use of a technology or methodology specified by the Secretary in guidance for rendering Protected Health Information unusable, unreadable, or indecipherable to unauthorized individuals.
- 18.3 Notwithstanding Section 18.1, in the event that return or destruction of Protected Health Information is not feasible or Business Associate determines that any such Protected Health Information is necessary for Business Associate to continue its proper management and administration or to carry out its legal responsibilities, Business Associate may retain that Protected Health Information for which destruction or return is infeasible or that Protected Health Information which is necessary for Business Associate to continue its proper management and administration or to carry out its legal responsibilities and shall return or destroy all other Protected Health Information.
- 18.3.1 Business Associate shall extend the protections of this Business Associate Agreement to such Protected Health Information, including continuing to use appropriate safeguards and continuing to comply with Subpart C of 45 C.F.R Part 164 with respect to Electronic Protected Health Information, to

prevent the Use or Disclosure of such information other than as provided for in Sections 2.5 and 2.6 for so long as such Protected Health Information is retained, and Business Associate shall not Use or Disclose such Protected Health Information other than for the purposes for which such Protected Health Information was retained.

18.3.2 Business Associate shall return or, if agreed to by Covered entity, destroy the Protected Health Information retained by Business Associate when it is no longer needed by Business Associate for Business Associate's proper management and administration or to carry out its legal responsibilities.

18.4 Business Associate shall ensure that all Protected Health Information created, maintained, or received by Subcontractors is returned or, if agreed to by Covered entity, destroyed as provided for in Section 18.2.

## **19.0 AUDIT, INSPECTION, AND EXAMINATION**

19.1 Covered Entity reserves the right to conduct a reasonable inspection of the facilities, systems, information systems, books, records, agreements, and policies and procedures relating to the Use or Disclosure of Protected Health Information for the purpose determining whether Business Associate is in compliance with the terms of this Business Associate Agreement and any non-compliance may be a basis for termination of this Business Associate Agreement and the applicable underlying Agreement, Contract, Master Agreement, Work Order, Purchase Order or other services arrangement, with or without payment, that gives rise to Contractor's status as a Business Associate, as provided for in Section 17.

19.2 Covered Entity and Business Associate shall mutually agree in advance upon the scope, timing, and location of any such inspection.

19.3 At Business Associate's request, and to the extent permitted by law, Covered Entity shall execute a nondisclosure agreement, upon terms and conditions mutually agreed to by the parties.

19.4 That Covered Entity inspects, fails to inspect, or has the right to inspect as provided for in Section 19.1 does not relieve Business Associate of its responsibility to comply with this Business Associate Agreement and/or the HIPAA Rules or impose on Covered Entity any responsibility for Business Associate's compliance with any applicable HIPAA Rules.

19.5 Covered Entity's failure to detect, its detection but failure to notify Business Associate, or its detection but failure to require remediation by Business Associate of an unsatisfactory practice by Business Associate, shall not constitute acceptance of such practice or a waiver of Covered Entity's enforcement rights under this Business Associate Agreement or the applicable underlying Agreement, Contract, Master Agreement, Work Order, Purchase Order or other services arrangement, with or without payment, that gives rise to Contractor's status as a Business Associate.



- 19.6 Section 19.1 is not intended by the parties to limit in any way the scope of Business Associate's obligations related to Inspection and/or Audit and/or similar review in the applicable underlying Agreement, Contract, Master Agreement, Work Order, Purchase Order, or other services arrangement, with or without payment, that gives rise to Contractor's status as a Business Associate.]

## **20.0 MISCELLANEOUS PROVISIONS**

- 20.1 Disclaimer. Covered Entity makes no warranty or representation that compliance by Business Associate with the terms and conditions of this Business Associate Agreement will be adequate or satisfactory to meet the business needs or legal obligations of Business Associate.
- 20.2 HIPAA Requirements. The Parties agree that the provisions under HIPAA Rules that are required by law to be incorporated into this Amendment are hereby incorporated into this Agreement.
- 20.3 No Third Party Beneficiaries. Nothing in this Business Associate Agreement shall confer upon any person other than the parties and their respective successors or assigns, any rights, remedies, obligations, or liabilities whatsoever.
- 20.4 Construction. In the event that a provision of this Business Associate Agreement is contrary to a provision of the applicable underlying Agreement, Contract, Master Agreement, Work Order, Purchase Order, or other services arrangement, with or without payment, that gives rise to Contractor's status as a Business Associate, the provision of this Business Associate Agreement shall control. Otherwise, this Business Associate Agreement shall be construed under, and in accordance with, the terms of the applicable underlying Agreement, Contract, Master Agreement, Work Order, Purchase Order or other services arrangement, with or without payment, that gives rise to Contractor's status as a Business Associate.
- 20.5 Regulatory References. A reference in this Business Associate Agreement to a section in the HIPAA Rules means the section as in effect or as amended.
- 20.6 Interpretation. Any ambiguity in this Business Associate Agreement shall be resolved in favor of a meaning that permits the parties to comply with the HIPAA Rules.
- 20.7 Amendment. The parties agree to take such action as is necessary to amend this Business Associate Agreement from time to time as is necessary for Covered Entity or Business Associate to comply with the requirements of the HIPAA Rules and any other privacy laws governing Protected Health Information.