



BOARD OF SUPERVISORS AGENDA ITEM REPORT
CONTRACTS / AWARDS / GRANTS

☐ Award ☒ Contract ☐ Grant

Requested Board Meeting Date: July 7, 2020

* = Mandatory, information must be provided

or Procurement Director Award ☐

***Contractor/Vendor Name/Grantor (DBA):**

The Arizona Board of Regents for and on behalf of Arizona State University ("ASU") Biodesign Institute

***Project Title/Description:**

COVID-19 Testing

***Purpose:**

Faculty and students at ASU will assist the Pima County Health Department ("PCHD") with high-throughput testing for COVID-19. This testing is certified by the Clinical Laboratory Improvement Amendments ("CLIA").

***Procurement Method:**

This IGA is a non-Procurement contract and not subject to Procurement rules.

***Program Goals/Predicted Outcomes:**

PCHD desires to engage ASU as a public-health partner in testing potential COVID-19 positive individuals in a timely manner to assist in their treatment and isolation, preventing further spread of COVID-19.

***Public Benefit:**

Testing is key part of the efforts to overcome the COVID-19 pandemic and safely return to full operation.

***Metrics Available to Measure Performance:**

- ASU will control the scheduling of the Services, but will make commercially reasonable efforts to meet the 48-hour time-lines established by County.
- # of tests

***Retroactive:**

No.

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Addendum

Contract / Award Information

Document Type: CT Department Code: GMI Contract Number (i.e.,15-123): 20-0390
Commencement Date: 07/07/2020 Termination Date: 07/06/2021 Prior Contract Number (Synergen/CMS): _____
☒ Expense Amount: \$* 2,000,000.00 ☐ Revenue Amount: \$ _____

***Funding Source(s) required:** At this time, the County will be funding this contract from the Health Special Revenue Fund, with expectation of reimbursement from Federal sources post-pandemic.

Funding from General Fund? ☐ Yes ☒ No If Yes \$ _____ % _____

Contract is fully or partially funded with Federal Funds? ☐ Yes ☒ No

If Yes, is the Contract to a vendor or subrecipient? _____

Were insurance or indemnity clauses modified? ☒ Yes ☐ No

If Yes, attach Risk's approval.

Vendor is using a Social Security Number? ☐ Yes ☒ No

If Yes, attach the required form per Administrative Procedure 22-10.

Amendment / Revised Award Information

Document Type: _____ Department Code: _____ Contract Number (i.e.,15-123): _____
Amendment No.: _____ AMS Version No.: _____
Commencement Date: _____ New Termination Date: _____
Prior Contract No. (Synergen/CMS): _____
☐ Expense or ☐ Revenue ☐ Increase ☐ Decrease Amount This Amendment: \$ _____
Is there revenue included? ☐ Yes ☐ No If Yes \$ _____

***Funding Source(s) required:**

Funding from General Fund? ☐ Yes ☐ No If Yes \$ _____ % _____

Grant/Amendment Information (for grants acceptance and awards) ☐ Award ☐ Amendment

Document Type: _____ Department Code: _____ Grant Number (i.e.,15-123): _____
Commencement Date: _____ Termination Date: _____ Amendment Number: _____
☐ Match Amount: \$ _____ ☐ Revenue Amount: \$ _____

***All Funding Source(s) required:**

***Match funding from General Fund?** ☐ Yes ☐ No If Yes \$ _____ % _____

***Match funding from other sources?** ☐ Yes ☐ No If Yes \$ _____ % _____

***Funding Source:** _____

***If Federal funds are received, is funding coming directly from the Federal government or passed through other organization(s)?** _____

Contact: Dana Y. Morales

Department: CED Telephone: 724-3511

Department Director Signature/Date: _____

Deputy County Administrator Signature/Date: _____

County Administrator Signature/Date: _____
(Required for Board Agenda/Addendum Items)



INTERGOVERNMENTAL AGREEMENT

This Intergovernmental Agreement ("Agreement") is entered into this ____ day of _____, 2020 (the "Effective Date") by and between Pima County, a political subdivision of the State of Arizona ("County"), and The Arizona Board of Regents for and on behalf of Arizona State University ("ASU").

RECITALS

- A. A.R.S. §§ 11-951, et. seq. provide that public agencies may enter into governmental agreements for the provisions of services or joint cooperative action.
- B. ASU's Biodesign Institute has available a high-throughput testing laboratory for COVID-19 testing. This testing is certified by the Clinical Laboratory Improvement Amendments (CLIA) process.
- C. County desires to engage ASU to test samples from individuals as directed by County, through its Health Department, and to perform COVID-19 testing, using the Biodesign laboratory (the "Services").
- D. County desires to engage ASU as a public-health partner in testing potential COVID-19 positive individuals in a timely manner to assist in their treatment and isolation, preventing further spread of COVID-19.
- E. ASU's Biodesign Institute desires to provide the testing services as set forth in this Agreement.
- F. The performance of the Services is consistent, compatible, and beneficial to the role and mission of ASU.

AGREEMENT

1. **Scope of Work.** ASU's Biodesign Institute will use reasonable efforts to provide the Services. The parties agree that ASU will have discretion to involve its students in the conduct and performance of the Services to the extent permitted by law. ASU's performance of the Services and its obligations under this Agreement are subject to and governed by the regulations and policies of the Arizona Board of Regents. County will arrange for the collection and delivery of specimens by any means chosen by County and acceptable to ASU. To the extent the collection and delivery of samples involves ASU, County will compensate ASU in accordance with Section 4 of this Agreement. County and ASU will cooperate to arrange a mutually agreeable schedule for delivery of specimens. ASU shall provide written test results by secure electronic means to Dr. Theresa Cullen, Pima County Health Department Director. ASU will report any positive test results to the authorities as required by applicable law. County shall be responsible for reporting all test results to individuals tested; ASU shall have no such obligation. ASU will use the specimens provided by County for lab testing only and may retain the test specimens and copies of the test results for internal quality control or other similar uses, but may not reuse the test specimens or test results for any purpose without the express written consent of County.

2. **Scheduling Services.** The scheduling of the Services will be arranged to avoid conflict with ASU's educational and research programs. ASU will control the scheduling of the Services, but will make commercially reasonable efforts to meet the 48-hour timeline established by County.

3. **Term and Termination.**

- 3.1 The term of this Agreement will be one year commencing on the Effective Date and will terminate as provided herein. The parties may modify or extend this Agreement at any time by mutual written consent.
- 3.2 Either party may terminate this Agreement at any time by giving the other party not less than fifteen (15) days prior written notice. If this Agreement is terminated by County, County will remain responsible for payment to ASU for all Services performed through the date of termination and for reimbursement to ASU of all non-cancelable commitments incurred in the performance of the Services. Upon termination, property purchased in furtherance of this Agreement will remain the property of the purchasing party, unless expressly specified otherwise.

4. **Compensation and Invoicing.**

- 4.1 **Rate Schedule.** County acknowledges and agrees that the rates herein are subject to change from time to time but that rates set forth on a Scope of Work will not change while work thereunder is in progress. In consideration for the Services, County will pay ASU as follows:
- 4.1.1 Sampling - For all of ASU's reasonably incurred expenses to perform the sampling, including without limitation, salary, materials and supplies, transportation costs, etc.
- 4.1.2 Laboratory Test - \$100 per test performed.
- 4.2 County will remit the amount of the contract price due for Services rendered under this Agreement upon receipt of invoices from ASU issued monthly for the duration of the period of performance. Invoices are due and payable within 30 days and are payable in full regardless of whether County is reimbursed for the testing, whether by patients, patient representatives, or third-party payors, including any government health care program. County will send checks or paper remittance advices to:
- KE Finance
Arizona State University
PO Box 876011
Tempe, AZ 85287-6011
- 4.3 ASU reserves the right to subject invoices not paid within thirty (30) days of the date the invoice is transmitted to County to a 1.5% per month late fee on the unpaid balance for any amounts not in dispute. ASU reserves the right to discontinue the Services if County fails to make payments when due. In the event of non-payment, ASU may terminate all further work on the Services and seek full payment from County for all work performed and all expenses incurred including allocable costs, pursuant to the termination clause

of this Agreement including the collection of payment. Should it become necessary for ASU to commence collection proceedings or retain an attorney to enforce any of the terms of this Agreement, County will pay all reasonable attorneys' fees and the costs of collection incurred by ASU.

5. **No Warranty, Limitation of Liability.**

5.1 County agrees that ASU does not make any representation or warranty for the accuracy of the Services. County further agrees that all Services are provided on an "AS-IS" and as available basis. ASU assumes no responsibility for the accuracy or lack of accuracy of any testing provided under the Services. County agrees to assume any risk for the inaccuracy of such testing.

5.2 **TO THE FULLEST EXTENT PERMITTED BY LAW, ASU and ASU'S BIODESIGN INSTITUTE DISCLAIM ALL WARRANTIES, EITHER EXPRESS OR IMPLIED, STATUTORY OR OTHERWISE, RELATED TO THE SERVICES INCLUDING, WITHOUT LIMITATION, ANY WARRANTY OF SATISFACTORY QUALITY, FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENT OF ANY THIRD-PARTY INTELLECTUAL PROPERTY OR PROPRIETARY RIGHTS.**

5.3 Limitation of Liability. County agrees, to the fullest extent permitted by law: 1) ASU shall not be liable to County for any consequential, incidental, indirect, special, reliance, punitive, or exemplary damages or losses, whether in contract, tort, or otherwise, that arise in any way out of this Agreement or the Services; and 2) IN NO EVENT WILL THE AGGREGATE LIABILITY OF ASU TO COUNTY IN ANY MATTER ARISING FROM, RELATING TO OR CONNECTED WITH THIS AGREEMENT OR THE SERVICES EXCEED \$100.

6. Health Insurance Portability and Accountability Act. The parties acknowledge that the County is a hybrid covered entity as described in 45 C.F.R. §160.103 of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), and is required to comply with the provisions of HIPAA with respect to safeguarding the privacy, confidentiality and security of protected health information. Contractor acknowledges that it may obtain confidential personal health information in the course of Contractor's performance under the terms of this Contract. "Confidential personal health information" includes information that could be used to identify a participant, information pertaining to the participant's care, treatment or experience in County's program, and information pertaining to the cost of, payment for, or collections activities related to participant's care, treatment and experience in County's program. Contractor agrees to maintain the privacy, confidentiality and security of information it may obtain in the course of its performance under this Contract. In particular, Contractor agrees that it is County's Business Associate and agrees to be bound by the Business Associate Agreement in Exhibit B (7 pages) which is incorporated into this agreement, and further specifically agrees that:

6.1 Any confidential personal health information that Contractor may obtain shall remain the sole property of the County; and

6.2 Contractor shall establish and maintain procedures and controls that are acceptable to County to assure that no confidential personal health information contained in its

records or obtained from County or from others in carrying out its functions under this Contract shall be used by or disclosed by Contractor, its agents, officers, employees or sub-contractors, except as required in the performance of its obligations under the terms of this Contract; and

- 6.3 Contractor shall not remove any confidential personal health information from County premises, if applicable; and
- 6.4 Any other information pertaining to individual persons shall not be divulged other than to employees or officers of Contractor as needed for the performance of its duties under this Contract, or to County.
7. **Disclaimers.** County agrees that ASU may obtain a signed disclaimer in the form substantially similar to that attached as Exhibit A, from any individual that ASU obtains a sample from.
8. **Authorization to Take Sample.** County represents and warrants to ASU that it has obtained all necessary authorizations and consents to take the samples and that the individuals to be tested have consented to be tested for COVID-19.
9. **Indemnification.** To the extent permitted by law, County will indemnify, defend, save and hold harmless the State of Arizona, its departments, agencies, boards, commissions, universities, and its and their officials, agents, and employees (collectively, "Indemnitee") for, from, and against any and all claims, actions, liabilities, damages, losses, or expenses (including court costs, attorneys' fees, and costs of claim processing, investigation, and litigation) arising out of or in any way related to this Agreement or the Services. County will be responsible for primary loss investigation, defense, and judgment costs where this indemnification is applicable.
10. **No University Endorsements.** In no event will County (or its successors, employees, agents and contractors) state or imply in any publication, advertisement or other medium that ASU has approved, endorsed or tested any product or service. In no event will ASU's performance of any Services hereunder be considered a test of the effectiveness or the basis for any endorsement of a product or service.
11. **Use of Names or Logos.** Neither party will use any names, service marks, trademarks, trade names, logos or other identifying names, domain names or identifying marks of the other party ("Marks"), or the name of any representative or employee of the other party in any sales promotion work or advertising, or any form of publicity, without the prior written permission of the party that owns the Marks in each instance. Use of any party's Marks must comply with the owning party's requirements, including using the "®" indication of a registered trademark where applicable.
12. **Similar Research.** Nothing in this Agreement will be construed to limit the freedom of ASU or of its researchers from engaging in similar services made under other grants, contracts or agreements with parties other than County.
13. **Export Controls.** County will notify ASU in writing if any technological information or data provided to ASU under this Agreement is subject to export controls under U.S. law or if technological information or data that County is requesting ASU to produce during the course of

work under this Agreement is expected to be subject to such controls. County will notify ASU of the applicable export controls (for example, Commerce Control List designations, reasons for control, countries for which an export license is required). ASU will have the right to decline export controlled information or tasks requiring production of such information.

14. **Independent Contractor.** Each party is an independent contractor and is independent of the other party. Under no circumstances will any employees of one party be deemed the employees of the other party for any purpose. This Agreement does not create a partnership, joint venture or agency relationship between the parties of any kind or nature. This Agreement does not create any fiduciary or other obligation between the parties, except for those obligations expressly and specifically set forth herein. Neither party will have any right, power, or authority under this Agreement to act as a legal representative of the other party, and neither party will have any power to obligate or bind the other or to make any representations, express or implied, on behalf of or in the name of the other in any manner or for any purpose whatsoever contrary to the provisions of this Agreement. Each party acknowledges that the relationship of the parties hereunder is non-exclusive.
15. **No Referral Obligation.** The parties each represent and warrant on behalf of itself, that the aggregate benefit given or received under this Agreement has been determined in advance through a process of arms-length negotiations that was intended to achieve an exchange of goods and/or services consistent with fair market value under the circumstances, and that any benefit given or received under this Agreement is not intended to induce, does not require, and is not contingent upon, the admission, recommendation or referral of any patient, directly or indirectly, and further, is not determined in any manner that takes into account the value of business generated between the parties. Nothing herein restricts or is intended to restrict the parties from making referrals for goods or services to any individual or entity. The parties represent and warrant that this Agreement does not involve the counseling or promotion of a business arrangement that violates federal or state law.
16. **Notices.** All notices, requests, demands and other communications hereunder will be deemed to have been duly given on the date of delivery if the same shall be in writing and be delivered (a) personally, (b) by registered or certified mail, postage prepaid, (c) by email or facsimile transmission, with a copy by regular mail or (d) by overnight delivery service and addressed to the recipient's business address.
17. **Force Majeure.** Neither Party is responsible for a failure to perform any obligation under this Agreement if such failure to perform is directly caused by a Force Majeure Event. A "Force Majeure Event" shall mean an event or circumstance that is beyond the reasonable control and without the fault or negligence of the Party impacted (other than for obligations to make payments when due under this Agreement), and that could not have been prevented by the reasonable diligence of the party. Without in any way limiting the foregoing, a Force Majeure Event may include, but are not restricted to (a) acts of God or of a public enemy, (b) acts of the Government in either its sovereign or contractual capacity, (c) fires, (d) floods, (e) epidemics or pandemics, (f) quarantine restrictions, (g) strikes, (h) freight embargoes; (i) failure or disruption of utilities or critical electronic systems, (j) mass health issues or disease, and (k) unusually severe weather. In the event that a Party is impacted by a Force Majeure Event, that Party will give prompt notice to the other Party and take commercially practical actions to mitigate the impacts

of the Force Majeure Event.

18. **Applicable Law.** Any dispute regarding or arising under this Agreement, or the interpretation of this Agreement, will be subject to and resolved in accordance with the laws of the State of Arizona, without regard to its conflicts of laws principles.
19. **Dispute Resolution.** In the event of any dispute, claim, question, or disagreement arising from or relating to this Agreement or the breach thereof, the parties hereto will use their reasonable efforts to settle the dispute, claim, question, or disagreement. To this effect, they will consult and negotiate with each other in good faith and, recognizing their mutual interests, attempt to reach a just and equitable solution satisfactory to both parties. In the event of litigation, as required by Arizona Revised Statutes ("A.R.S.") §12-1518, the parties agree to make use of arbitration in all contracts that are subject to mandatory arbitration pursuant to rules adopted under A.R.S. §12-133.
20. **Medicare Access to Books and Records.** For the purposes of implementing Section 1861(v)(1)(I) of the Social Security Act, as amended, and any regulations promulgated pursuant thereto, ASU agrees that until the expiration of four (4) years after the furnishing of the Services, it will make available, upon written request to the Secretary of the US Department of Health and Human Services or upon request to the Comptroller General, or any of their duly authorized representatives, the contracts, and books, documents and records of ASU necessary to certify the nature and extent of such costs
21. **Assignment.** Neither party will assign or transfer any interest in this Agreement without the prior written approval of the other party. Any attempted assignment in violation of this provision will be null and void. Subject to the foregoing, this Agreement will be binding upon the permitted successors and permitted assigns or other permitted transferees of the parties.
22. **Recitals and Exhibits.** All recitals herein, and all exhibits attached hereto and referred to herein, are integral and material parts of this Agreement.
23. **Severability.** If any provision of this Agreement shall for any reason be found invalid, illegal, unenforceable, or in conflict with any valid controlling law: (a) such provision will be separated from this Agreement; (b) such invalidity, illegality, unenforceability, or conflict will not affect any other provision hereof; and (c) this Agreement will be interpreted and construed as if such provision, to the extent the same shall have been held invalid, illegal, unenforceable, or in conflict, had never been contained herein.
24. **Waiver.** The waiver of a breach hereunder may be effected only by a writing signed by the waiving party and will not constitute, or be held to be, a waiver of any other or subsequent breach or to affect in any way the effectiveness or enforceability of the provision in question.
25. **Modification.** Any modification or amendment of this Agreement will be effective only if made in writing and signed by both parties.
26. **No Third Party Beneficiaries.** Nothing in this Agreement, express or implied, is intended or will be construed to confer upon any person or entity, other than the parties and their respective

successors and assigns permitted by this Agreement, any right, remedy or claim under or by reason of this Agreement.

27. **Merger and Integration.** This Agreement contains the entire understanding between the parties concerning the subject matter of this Agreement and supersedes any and all prior understandings, agreements, representations, and warranties, express or implied, written or oral, between the parties concerning the subject matter of this Agreement.
28. **Nondiscrimination.** The parties agree to comply with all applicable state and federal laws, rules, regulations and executive orders governing equal employment opportunity, immigration and nondiscrimination, including the Americans with Disabilities Act.
29. **Conflict of Interest.** In accordance with A.R.S. § 38-511, either party may cancel this Agreement within three years after the execution of this Agreement, without penalty or further obligation, if any person significantly involved in initiating, negotiating, securing, drafting or creating this Agreement on behalf of that party, at any time while this Agreement or any extension thereof is in effect, is an employee or agent of any other party to this Agreement in any capacity or a consultant to any other party with respect to the subject matter of this Agreement.
30. **Failure of Legislature to appropriate.** In accordance with A.R.S. § 35-154, if ASU's performance under this Agreement depends on the appropriation of funds by the Arizona Legislature, and if the Legislature fails to appropriate the funds necessary for performance, then ASU may provide written notice of this to County and cancel this Agreement without further obligation of ASU. Appropriation is a legislative act and is beyond the control of ASU. Additionally, notwithstanding any other provision in this IGA, County may terminate this IGA if for any reason the Pima County Board of Supervisors does not appropriate sufficient monies for the purpose of maintaining the IGA. In the event of such termination, County shall have any further obligation to ASU other than to pay for any Services already rendered.
31. **Counterparts.** This Agreement may be executed in one or more counterparts, each of which will be deemed an original, but all of which taken together will constitute one and the same instrument, and photocopy, facsimile, electronic and other copies will have the same effect for all purposes as an ink-signed original.

[SIGNATURES ON NEXT PAGE.]

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed by their duly authorized representatives on the respective dates entered below.

**THE ARIZONA BOARD OF REGENTS
FOR AND ON BEHALF OF
ARIZONA STATE UNIVERSITY**

PIMA COUNTY

By: _____

By: _____

Name: _____

Name: _____

Title: _____

Title: _____

Date: _____

Date: _____

INTERGOVERNMENTAL AGREEMENT DETERMINATION

In accordance with A.R.S. § 11-952, this Agreement has been reviewed by the undersigned who have determined that this Agreement is in appropriate form and is within the powers and authority of the respective parties.

Pima County

The Arizona Board of Regents for and on Behalf
of Arizona State University

By:  _____

By: _____

Deputy County Attorney

Counsel for ASU

Date: 7/1/2020

Date: _____

EXHIBIT A

Patient Disclaimer

By signing below, you understand and agree to the following:

1. The Arizona Board of Regents for and on behalf of Arizona State University ("ASU") and The Biodesign Institute make no representation and assume no responsibility for the accuracy of the testing – all testing results are provided on an "AS-IS" and as available basis.
2. ASU and The Biodesign Institute **TO THE FULLEST EXTENT PERMITTED BY LAW, DISCLAIM ALL WARRANTIES, EITHER EXPRESS OR IMPLIED, STATUTORY OR OTHERWISE, RELATED TO THE COVID-19 TESTING INCLUDING WITHOUT LIMITATION ANY WARRANTY OF SATISFACTORY QUALITY, FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENT OF ANY THIRD PARTY INTELLECTUAL PROPERTY OR PROPRIETARY RIGHTS.**
3. To the fullest extent permitted by applicable law, ASU and The Biodesign Institute do not warrant the accuracy or completeness of the testing provided by the Biodesign Institute.
4. Limitation of Liability. You hereby agree that to the fullest extent permitted by law:
 - a. ASU and The Biodesign Institute shall not be liable to you, or any of your heirs or assigns, for any consequential, incidental, indirect, special, reliance, punitive, or exemplary damages or losses, whether in contract, tort, or otherwise.
 - b. IN NO EVENT WILL THE AGGREGATE LIABILITY OF ASU OR THE BIODESIGN INSTITUTE IN ANY MATTER ARISING FROM, RELATING TO OR CONNECTED WITH THIS MATTER EXCEED \$100.

Name: _____

Signature: _____

Date: _____

EXHIBIT B

WHEREAS, Pima County, on behalf of the Pima County Health Department ("Covered Entity"), and Arizona State University ("Business Associate") (each, a "Party," and collectively, the "Parties") wish to enter into a Business Associate Agreement to ensure compliance with the Privacy, Security, Breach Notification, and Enforcement Rules of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA Privacy and Security Rules") (45 C.F.R. Parts 160 and 164); and

WHEREAS, the Health Information Technology for Economic and Clinical Health ("HITECH") Act of the American Recovery and Reinvestment Act of 2009, Pub. L. 111-5, modified the HIPAA Privacy and Security Rules (hereinafter, all references to the "HIPAA Privacy and Security Rules" include all amendments thereto set forth in the HITECH Act and any accompanying regulations); and

WHEREAS, the Parties have entered into a written or oral arrangement or arrangements (the "Underlying Agreement") whereby Business Associate will provide certain services to Covered Entity that require Business Associate to create, receive, maintain, or transmit Protected Health Information ("PHI") on Covered Entity's behalf, and accordingly Business Associate may be considered a "business associate" of Covered Entity as defined in the HIPAA Privacy and Security Rules; and

WHEREAS, Business Associate and Covered Entity wish to comply with the HIPAA Privacy and Security Rules, and Business Associate wishes to honor its obligations as a business associate to Covered Entity.

THEREFORE, in consideration of the Parties' continuing obligations under the Underlying Agreement, the Parties agree to the provisions of this Business Associate Agreement ("Agreement").

Except as otherwise defined herein, any and all capitalized terms in this Agreement shall have the definitions set forth in the HIPAA Privacy and Security Rules. In the event of an inconsistency between the provisions of this Agreement and mandatory provisions of the HIPAA Privacy and Security Rules, as amended, the HIPAA Privacy and Security Rules in effect at the time the inconsistency is discovered shall control. Where provisions of this Agreement are different than those mandated by the HIPAA Privacy and Security Rules, but are nonetheless permitted by the HIPAA Privacy and Security Rules, the provisions of this Agreement shall control.

I. PERMITTED USES AND DISCLOSURES BY BUSINESS ASSOCIATE

A. Business Associate may use or disclose PHI to perform functions, activities, or services for, or on behalf of, Covered Entity as specified in the Underlying Agreement, provided that such use or disclosure would not violate the HIPAA Privacy and Security Rules if done by Covered Entity.

B. Business Associate may use PHI in its possession for its proper management and administration and to fulfill any present or future legal responsibilities of Business Associate, provided that such uses are permitted under state and federal confidentiality laws.

C. Business Associate may disclose PHI in its possession to third parties for the purposes of its proper management and administration or to fulfill any present or future legal responsibilities of Business Associate, provided that:

1. the disclosures are required by law; or

2. Business Associate obtains reasonable assurances from the third parties to whom the PHI is disclosed that the information will remain confidential and be used or further disclosed only as required by law or for the purpose for which it was disclosed to the third party, and that such third parties will notify Business Associate of any instances of which they are aware in which the confidentiality of the information has been breached.

D. Until such time as the Secretary issues regulations pursuant to the HITECH Act specifying what constitutes "minimum necessary" for purposes of the HIPAA Privacy and Security Rules, Business Associate shall, to the extent practicable, access, use, and request only PHI that is contained in a limited data set (as defined in 45 C.F.R. § 164.514(e)(2)), unless Business Associate requires certain direct identifiers in order to accomplish the intended purpose of the access, use, or request, in which event Business Associate may access, use, or request only the minimum necessary amount of PHI to accomplish the intended purpose of the access, use, or request.

II. OBLIGATIONS AND ACTIVITIES OF BUSINESS ASSOCIATE

A. Business Associate agrees not to use or further disclose PHI other than as permitted or required by this Agreement or the Underlying Agreement or as required by state and federal law.

B. Business Associate agrees to use appropriate safeguards and to comply, where applicable, with 45 C.F.R. Part 164, Subpart C with respect to Electronic Protected Health Information, to prevent use or disclosure of PHI other than as provided for by this Agreement. Specifically, Business Associate will:

1. implement the administrative, physical, and technical safeguards set forth in 45 C.F.R. §§ 164.308, 164.310, and 164.312 that reasonably and appropriately protect the confidentiality, integrity, and availability of any PHI that it creates, receives, maintains, or transmits on behalf of Covered Entity, and, in accordance with 45 C.F.R. § 164.316, implement and maintain reasonable and appropriate policies and procedures to enable it to comply with the requirements outlined in 45 C.F.R. §§ 164.308, 164.310, and 164.312; and

2. report to Covered Entity any Security Incident, and any use or disclosure of PHI that is not provided for by this Agreement, of which Business Associate becomes aware without unreasonable delay and in no case later than thirty (30) calendar days after discovery.

C. Business Associate shall require each subcontractor that creates, receives, maintains, or transmits PHI on its behalf to enter into a business associate agreement or equivalent agreement containing the same restrictions on access, use, and disclosure of PHI as those applicable to Business Associate under this Agreement. Furthermore, to the extent that Business Associate provides Electronic PHI to a subcontractor, Business Associate shall require such subcontractor to comply with all applicable provisions of 45 C.F.R. Part 164, Subpart C.

D. Business Associate agrees to comply with any requests for restrictions on certain disclosures of PHI to which Covered Entity has agreed in accordance with 45 C.F.R. § 164.522 of which Business Associate has been notified by Covered Entity.

E. If Business Associate maintains a designated record set on behalf of Covered Entity, at the request of Covered Entity and in a reasonable time and manner, Business Associate agrees to make available PHI required for Covered Entity to respond to an individual's request for access to his or her PHI in accordance with 45 C.F.R. § 164.524. If Business Associate maintains PHI in an electronic designated record set, it agrees to make such PHI available electronically to Covered Entity or, upon Covered Entity's specific request, to the applicable individual or to a person or entity specifically designated by such individual, upon such individual's request.

F. If Business Associate maintains a designated record set on behalf of Covered Entity, at the request of Covered Entity and in a reasonable time and manner, Business Associate agrees to make available PHI required for amendment by Covered Entity in accordance with the requirements of 45 C.F.R. § 164.526.

G. Business Associate agrees to document any disclosures of Protected Health Information, and to make PHI available for purposes of accounting of disclosures, as required by 45 C.F.R. § 164.528.

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

I. Business Associate agrees that it will make its internal practices, books, and records relating to the use and disclosure of PHI received from, or created or received by Business Associate on behalf of, Covered Entity, available to the Secretary, in a time and manner designated by the Secretary, to enable the Secretary to determine Business Associate's or Covered Entity's compliance with the HIPAA Privacy and Security Rules. Business Associate also shall cooperate with the Secretary and, upon the Secretary's request, pursuant to 45 C.F.R. § 160.310, shall disclose PHI to the Secretary to enable the Secretary to investigate and review Business Associate's or Covered Entity's compliance with the HIPAA Privacy and Security Rules.

J. Unless expressly authorized in the Underlying Agreement, Business Associate shall not:

1. use PHI for marketing or fundraising;

2. use PHI to create a limited data set or to de-identify the information;
3. use PHI to provide data aggregation services relating to the health care operations of Covered Entity; or
4. use or disclose PHI in exchange for remuneration of any kind, whether directly or indirectly, financial or non-financial, other than such remuneration as Business Associate receives from Covered Entity in exchange for Business Associate's provision of the services specified in the Underlying Agreement.
5. Prior express written authorization from Covered Entity is required for Business Associate to access, store, share, maintain, transmit, use, or disclose PHI in any form via any medium with any entity or person, including the Business Associate's employees and subcontractors, beyond the boundaries and jurisdiction of the United States. Authorization may be granted in the sole discretion of Covered Entity and, if granted, will be subject to additional conditions with which Business Associate must agree.

III. BUSINESS ASSOCIATE'S MITIGATION AND BREACH NOTIFICATION OBLIGATIONS

A. Business Associate agrees to mitigate, to the extent practicable, any harmful effect that is known to Business Associate of a use or disclosure of PHI by Business Associate in violation of the requirements of this Agreement.

B. Following the discovery of a Breach of Unsecured PHI ("Breach"), Business Associate shall notify Covered Entity of such Breach without unreasonable delay and in no case later than thirty (30) calendar days after discovery of the Breach, and shall assist in Covered Entity's breach analysis process, including risk assessment, if requested. A Breach shall be treated as discovered by Business Associate as of the first day on which such Breach is known to Business Associate or, through the exercise of reasonable diligence, would have been known to Business Associate. The Breach notification shall be provided to Covered Entity in the manner specified in 45 C.F.R. § 164.410(c) and shall include the information set forth therein to the extent known. If, following the Breach notification, Business Associate learns additional details about the Breach, Business Associate shall notify Covered Entity promptly as such information becomes available. Covered Entity shall determine whether Business Associate or Covered Entity will be responsible for providing notification of any Breach to affected individuals, the media, the Secretary, and/or any other parties required to be notified under the HIPAA Privacy and Security Rules or other applicable law. If Covered Entity determines that Business Associate will be responsible for providing such notification, Business Associate may not carry out notification until Covered Entity approves the proposed notices in writing.

C. Notwithstanding the provisions of Section III.B., above, if a law enforcement official states to Business Associate that notification of a Breach would impede a criminal investigation or cause damage to national security, then:

1. if the statement is in writing and specifies the time for which a delay is required, Business Associate shall delay such notification for the time period specified by the official; or

2. if the statement is made orally, Business Associate shall document the statement, including the identity of the official making it, and delay such notification for no longer than thirty (30) days from the date of the oral statement unless the official submits a written statement during that time.

Following the period of time specified by the official, Business Associate shall promptly deliver a copy of the official's statement to Covered Entity.

D. Business Associate shall bear Covered Entity's costs of any Breach and resultant notifications, if applicable, to the extent the Breach arises from Business Associate's negligence, willful misconduct, violation of law, violation of the Underlying Agreement, or violation of this Agreement.

IV. OBLIGATIONS OF COVERED ENTITY

A. Upon request of Business Associate, Covered Entity shall provide Business Associate with the notice of privacy practices that Covered Entity produces in accordance with 45 C.F.R. § 164.520.

B. Covered Entity shall provide Business Associate with any changes in, or revocation of, permission by an individual to use or disclose Protected Health Information, if such changes could reasonably be expected to affect Business Associate's permitted or required uses and disclosures.

C. Covered Entity shall notify Business Associate of any restriction on the use or disclosure of PHI to which Covered Entity has agreed in accordance with 45 C.F.R. § 164.522, and Covered Entity shall inform Business Associate of the termination of any such restriction, and the effect that such termination shall have, if any, upon Business Associate's use and disclosure of such Protected Health Information.

V. TERM AND TERMINATION

A. Term. The Term of this Agreement shall be effective as of the first effective date of any Underlying Agreement, and shall terminate upon later of the following events: (i) in accordance with Section V.C., when all of the PHI provided by Covered Entity to Business Associate or created or received by Business Associate on behalf of Covered Entity is returned to Covered Entity or destroyed (and a certificate of destruction is provided) or, if such return or destruction is infeasible, when protections are extended to such information; or (ii) upon the expiration or termination of the last of the Underlying Agreement.

B. Termination. Upon either Party's knowledge of a material breach by the other Party of its obligations under this Agreement, the non-breaching Party shall, within twenty (20) days of

that determination, notify the breaching Party, and the breaching Party shall have thirty (30) days from receipt of that notice to cure the breach or end the violation. If the breaching Party fails to take reasonable steps to effect such a cure within such time period, the non-breaching Party may terminate this Agreement and the Underlying Agreement without penalty.

Where either Party has knowledge of a material breach by the other Party and determines that cure is infeasible, prior notice of the breach is not required, and the non-breaching Party shall terminate the portion of the Underlying Agreement affected by the breach without penalty.

C. Effect of Termination.

1. Except as provided in paragraph 2 of this subsection C., upon termination of this Agreement, the Underlying Agreement or upon request of Covered Entity, whichever occurs first, Business Associate shall return or destroy all PHI received from Covered Entity, or created or received by Business Associate on behalf of Covered Entity. This provision shall apply to PHI that is in the possession of subcontractors of Business Associate. Neither Business Associate nor its subcontractors shall retain copies of the PHI except as required by law.

2. In the event that Business Associate determines that returning or destroying the PHI is infeasible, Business Associate shall provide within ten (10) days to Covered Entity notification of the conditions that make return or destruction infeasible. Upon mutual agreement of the Parties that return or destruction of PHI is infeasible, Business Associate, and its applicable subcontractors, shall extend the protections of this Agreement to such PHI and limit further uses and disclosures of such PHI to those purposes that make the return or destruction infeasible, for so long as Business Associate and its applicable subcontractors maintain such Protected Health Information.

VI. MISCELLANEOUS

A. No Rights in Third Parties. Except as expressly stated herein or in the HIPAA Privacy and Security Rules, the Parties to this Agreement do not intend to create any rights in any third parties.

B. Survival. The obligations of Business Associate under Section V.C. of this Agreement shall survive the expiration, termination, or cancellation of this Agreement, the Underlying Agreement, and/or the business relationship of the Parties, and shall continue to bind Business Associate, its agents, employees, contractors, successors, and assigns as set forth herein.

C. Amendment. The Parties agree that this Agreement will be amended automatically to conform to any changes in the HIPAA Privacy and Security Rules as are necessary for each of them to comply with the current requirements of the HIPAA Privacy and Security Rules and the Health Insurance Portability and Accountability Act, unless a particular statutory or regulatory provision requires that the terms of this Agreement be amended to reflect any such change. In those instances where an amendment to this Agreement is required by law, the Parties shall negotiate in good faith to amend the terms of this Agreement within sixty (60) days of the effective date of the law or final rule requiring the amendment. If, following such period of good faith

negotiations, the Parties cannot agree upon an amendment to implement the requirements of said law or final rule, then either Party may terminate this Agreement and the Underlying Agreement upon ten (10) days written notice to the other Party. Except as provided above, this Agreement may be amended or modified only in a writing signed by the Parties.

D. Assignment. Neither Party may assign its respective rights and obligations under this Agreement without the prior written consent of the other Party.

E. Independent Contractor. None of the provisions of this Agreement are intended to create, nor will they be deemed to create, any relationship between the Parties other than that of independent parties contracting with each other solely for the purposes of effecting the provisions of this Agreement and any other agreements between the Parties evidencing their business relationship. Nothing in this Agreement creates or is intended to create an agency relationship.

F. Governing Law. To the extent this Agreement is not governed exclusively by the HIPAA Privacy and Security Rules or other provisions of federal statutory or regulatory law, it will be governed by and construed in accordance with the laws of the state in which Covered Entity has its principal place of business.

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

H. Interpretation. Any ambiguity of this Agreement shall be resolved in favor of a meaning that permits Covered Entity and Business Associate to comply with the HIPAA Privacy and Security Rules.

I. Severability. In the event that any provision of this Agreement is held by a court of competent jurisdiction to be invalid or unenforceable, the remainder of the provisions of this Agreement will remain in full force and effect.

J. Notice. Any notification required in this Agreement shall be made in writing to the representative of the other Party who signed this Agreement or the person currently serving in that representative's position with the other Party.

K. Entire Agreement. This Agreement constitutes the entire understanding of the Parties with respect to the subject matter hereof and supersedes all prior agreements, oral or written. In the event of any inconsistency between this Agreement and any other agreement between the Parties concerning the use and disclosure of PHI and the Parties' obligations with respect thereto, the terms of this Agreement shall control.

L. Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original but all of which together shall constitute one and the same Agreement.