



**BOARD OF SUPERVISORS AGENDA ITEM REPORT**  
**CONTRACTS / AWARDS / GRANTS**

☐ Award ☒ Contract ☐ Grant

Requested Board Meeting Date: 10/06/20

\* = Mandatory, information must be provided

or Procurement Director Award ☐

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

El Rio Santa Cruz Neighborhood Health Center, Inc. (Headquarters: Tucson, AZ), Rescue Me Wellness, L.L.C.  
(Headquarters: Tucson, AZ)

**\*Project Title/Description:**

COVID-19 Testing Services

**\*Purpose:**

Award: Master Agreement No. MA-PO-21-057. This Master Agreement is for an initial term of one (1) year in the shared annual award amount of \$4,000,000.00 and includes Four (4) one-year renewal options.

**\*Procurement Method:**

Pursuant to Pima County Procurement Code 11.24.10, Cooperative procurement authorized, for Requisition No. RQM 21-081, the Procurement Director approved the use of City of Tucson Contract Nos. 202518-01 and 202518-02, which were awarded through competitive procedures reasonably similar to those set forth by Pima County Procurement Code.

PRCUID: 392658

Attachment: Cooperative Procurement Agreement

**\*Program Goals/Predicted Outcomes:**

Increased COVID-19 testing availability for Pima County Residents with a rapid response time to allow for effective measures to reduce the spread of COVID-19.

**\*Public Benefit:**

Rapid identification of positive COVID-19 cases, allowing effective isolation of positive cases and rapid contact tracing to mitigate spread.

**\*Metrics Available to Measure Performance:**

Test result return time, positivity rate, review and audit of infection control procedures, standard quality assurance.

**\*Retroactive:**

No

PRC 392658 MA-PO-21-057  
MA

TO: COB 9/29/20  
ver. 1  
pages - 28

**Contract / Award Information**

Document Type: MA Department Code: PO Contract Number (i.e., 15-123): 21-057  
 Commencement Date: 10/06/20 Termination Date: 10/05/21 Prior Contract Number (Synergen/CMS): \_\_\_\_\_  
☒ Expense Amount: \$\* 4,000,000.00 ☐ Revenue Amount: \$ \_\_\_\_\_

\*Funding Source(s) required: Various Grant Funds

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: \_\_\_\_\_

☐ 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: Scott Loomis  
Digitally signed by Scott Loomis  
 DN: cn=Scott Loomis, o=Pima County,  
 email=scott.loomis@pima.gov, ou=US  
 Date: 2020.09.29 07:18:02 -0700

Ana Wilber  
Digitally signed by Ana Wilber  
 Date: 2020.09.29 07:50:11  
 -0700

Department: Procurement

Mary Jo Furphy

Telephone: 520-724-8272

Department Director Signature/Date: [Signature] 09/29/20

Deputy County Administrator Signature/Date: [Signature] 22 Sep 20

County Administrator Signature/Date: C. R. [Signature] 9/29/20  
 (Required for Board Agenda/Addendum Items)

**Pima County Procurement Department**

**Administering Department:** Health Department

**Project:** COVID-19 Testing Services

**Contractor:** El Rio Santa Cruz Neighborhood Health Center, Inc.  
839 W. Congress Street  
Tucson, Arizona 85745

Rescue Me Wellness, L.L.C.  
3283 E. 5<sup>th</sup> Street  
Tucson, Arizona 85716

**Amount:** \$4,000,000.00

**Contract No.:** MA-PO-21-057

**Funding:** Various Grant Funds

**COOPERATIVE PROCUREMENT AGREEMENT**

**1. Parties, Background and Purpose.**

- 1.1. Parties. This Contract is between Pima County, a political subdivision of the State of Arizona ("County"), and El Rio Santa Cruz Neighborhood Health Center, Inc. and Rescue Me Wellness, L.L.C. ("Contractors").
- 1.2. Purpose. The Pima County Health Department requires COVID-19 Testing Services due to the ongoing COVID-19 Pandemic.
- 1.3. Authority. County is authorized by Pima County Code § 11.24.010 and A.R.S. § 41-2632 to enter into cooperative purchasing arrangements. County has entered into such an agreement with the City of Tucson (County contract no. 12563).
- 1.4. Contract.
  - 1.4.1. The City of Tucson entered into contract Nos. 202518-01 and 202518-02 for specified goods and services with El Rio Santa Cruz Neighborhood Health Center, Inc. a corporation registered in the State of Arizona, and Rescue Me Wellness, L.L.C., a limited liability company registered in the State of Arizona ("Contractors"), which is currently in effect ("City of Tucson Contracts"). The "City of Tucson Contracts" are incorporated into this Contract by this reference.
  - 1.4.2. Selection 1 of Special Terms and Conditions of the City of Tucson Contract provides that another governmental entity with which the City of Tucson has a cooperative purchasing agreement may, with Contractor's approval, purchase products and services at the same prices and under the same terms as in the City of Tucson Contract.

**2. Term.**

- 2.1. Initial Term. The term of this Contract commences on October 6, 2020 and will terminate on October 5, 2021 ("Initial Term"). "Term," when used in this Contract,

means the Initial Term plus any exercised extension options under Section 2.2. If the commencement date of the Initial Term is before the signature date of the last party to execute this Contract, the parties will, for all purposes, deem the Contract to have been in effect as of the commencement date.

2.2. Extension Options. County may renew this Contract for up to four (4) additional periods of up to 1 year each (each an "Extension Option"). An Extension Option will be effective only upon execution by the Parties of a formal written amendment.

3. **Scope of Services**. Contractor will provide County with the services as described in the City of Tucson Contract with further details as described in **Exhibit A Scope Of Services (2 pages)**, at the dates and times described on **Exhibit A**. The Services must comply with all requirements and specifications in the Solicitation.

4. **Compensation and Payment**.

4.1. Rates; Adjustment. County will pay Contractors at the rates set forth in **Exhibit B Compensation and Payment (1 page)**. Those rates will remain in effect during an Extension Option period unless Contractor, at least 90 days before the end of the then-existing Term, or at the time the County informs Contractor that the County intends to extend the Term, if that is earlier, notifies County in writing of any adjustments to those rates, and the reasons for the adjustments.

4.2. Not-To-Exceed (NTE) Amount. County's total payments to Contractors under this Contract, including any sales taxes, may not exceed \$4,000,000.00 (the "NTE Amount"). The NTE Amount can only be changed by a formal written amendment executed by the Parties. Contractor is not required to provide any services, payment for which will cause the County's total payments under this Contract to exceed the NTE Amount; if Contractor does so, it is at the Contractor's own risk.

4.3. Sales Taxes. The payment amounts or rates in "**Exhibit B**" do not include sales taxes. Contractor may invoice County for sales taxes that Contractor is required to pay under this Contract. Contractor will show sales taxes as a separate line item on invoices.

4.4. Timing of Invoices. Contractor will invoice County on a monthly basis unless a different billing period is set forth in "**Exhibit B**". County must receive invoices no more than 30 days after the end of the billing period in which Contractor delivered the invoiced products or services to County. County may refuse to pay for any product or service for which Contractor does not timely invoice the County and, pursuant to A.R.S. § 11-622(C), will not pay for any product or service invoiced more than 6-months late.

4.5. Content of Invoices. Contractor will include detailed documentation in support of its invoices and assign each amount billed to an appropriate line item.

4.6. Invoice Submittal. Invoices are to be sent to:

Pima County Finance & Risk Management – Accounts Payable  
P.O. Box 791  
Tucson, AZ 85701

4.7. Invoice Adjustments. County may, at any time during the Term and during the retention period set forth in Section 23 below, question any payment under this Contract. If County raises a question about the propriety of a past payment, Contractor will cooperate with County in reviewing the payment. County may set-off any overpayment against amounts due to Contractor under this or any other contract between County and Contractor. Contractor will promptly pay to County any overpayment that County cannot recover by set-off.

5. **Insurance**. Contractor will procure and maintain at its own expense insurance policies (the “**Required Insurance**”) satisfying the below requirements (the “**Insurance Requirements**”) until all of its obligations under this Contract have been met. The below Insurance Requirements are minimum requirements for this Contract and in no way limit Contractor’s indemnity obligations under this Contract. The County in no way warrants that the required insurance is sufficient to protect the Contractor for liabilities that may arise from or relate to this Contract. If necessary, Contractor may obtain commercial umbrella or excess insurance to satisfy the Insurance Requirements.

5.1. Insurance Coverages and Limits. Contractor will procure and maintain, until all of its obligations have been discharged, coverage with limits of liability not less than those stated below. Coverage must be placed with insurers acceptable to the County with A.M. Best rating of not less than A-VII, unless otherwise approved by the County.

5.1.1. Commercial General Liability (CGL). Occurrence Form with limits not less than \$2,000,000 Each Occurrence and \$2,000,000 General Aggregate. Policy shall include cover for liability arising from premises, operations, independent contractors, personal injury, bodily injury, broad form contractual liability and products-completed operations. Any standard coverages excluded from the CGL policy, such as products/completed operations, etc. shall be covered by endorsement or separate policy and documented on the Certificates of Insurance.

5.1.2. Business Automobile Liability. Coverage for bodily injury and property damage on any owned, leased, hired, and/or non-owned autos assigned to or used in the performance of this Contract with minimum limits not less than \$1,000,000 Each Accident.

5.1.3. Workers’ Compensation and Employers’ Liability. Statutory coverage for Workers’ Compensation. Workers’ Compensation statutory coverage is compulsory for employers of one or more employees. Employers Liability coverage with limits of \$1,000,000 each accident and \$1,000,000 each employee – disease.

5.1.4. Medical Malpractice. This insurance is required for work from healthcare professionals whose coverage is excluded from the above CGL policy. The policy limits shall be not less than \$2,000,000 Each Claim and \$2,000,000 Annual Aggregate.

5.2. Additional Insurance Requirements. The policies shall include, or be endorsed to include, as required by this written agreement, the following provisions.

5.2.1. Claims Made Coverage. If any part of the Required Insurance is written on a claims-made basis, any policy retroactive date must precede the effective date of

this Contract, and Contractor must maintain such coverage for a period of not less than three (3) years following Contract expiration, termination or cancellation.

5.2.2. Additional Insured Endorsement. The General Liability and Business Automobile Liability shall each be endorsed to include County, its departments, districts, officials, agents, and employees as additional insureds with respect to liability arising out of the activities performed by or on behalf of the Contractor.

5.2.3. Subrogation Endorsement. The General Liability, Business Automobile Liability, Workers' Compensation and Technology E&O Policies shall each contain a waiver of subrogation endorsement in favor of County, and its departments, districts, officials, agents, and employees for losses arising from work performed by or on behalf of the Contractor.

5.2.4. Primary Insurance Endorsement. The Required Insurance policies must stipulate that they are primary and that any insurance carried by County, or its agents, officials, or employees, is excess and not contributory insurance.

5.2.5. The Required Insurance policies may not obligate the County to pay any portion of a Contractor's deductible or Self Insurance Retention (SIR). Insurance provided by the Contractor shall not limit the Contractor's liability assumed under the indemnification provisions of this Contract.

5.2.6. Subcontractors. Contractor must either (a) include all subcontractors as additional insureds under its Required Insurance policies, or (b) require each subcontractor to separately meet all Insurance Requirements and verify that each subcontractor has done so, Contractor must furnish, if requested by County, appropriate insurance certificates for each subcontractor. Contractor must obtain County's approval of any subcontractor request to modify the Insurance Requirements as to that subcontractor.

5.3. Notice of Cancellation. For each insurance policy required by the insurance provisions of this Contract, the Contractor must provide to County, within two (2) business days of receipt of notice, if a policy is suspended, voided, or cancelled for any reason. Such notice shall be mailed, emailed, hand-delivered or sent by facsimile transmission to the County's Contracting Representative. Notice shall include County's project or contract number and project description.

#### 5.4. Verification of Coverage.

5.4.1. Contractor must furnish County with a certificate of insurance (valid ACORD form or equivalent approved by County) for each Required Insurance policy, which must specify that the policy has all the required endorsements, and must include County's project or contract number and project description. Each certificate must be signed by an authorized representative of the insurer.

5.4.2. Contractor must provide the certificates to County before work commences. Each Required Insurance policy must be in effect at least 10 days before work under this Contract commences. Contractor must provide County a renewal certificate not less than 15 days prior to a Required Insurance policy's expiration date. Failure to

maintain the Required Insurance policies, or to provide evidence of renewal, is a material breach of this Contract.

5.4.3. County may at any time require Contractor to provide a complete copy of any Required Insurance policy or endorsement. Note: Contractors for larger projects must provide actual copies of the additional insured and subrogation endorsements.

5.4.4. All insurance certificates must be sent directly to the appropriate County Department.

5.5 Approval and Modifications. County's Risk Manager may modify the Insurance Requirements at any point during the Term of this Contract. This can be done administratively, with written notice from the Risk Manager, and does not require a formal Contract amendment. Neither the County's failure to obtain a required insurance certificate or endorsement, the County's failure to object to a non-complying insurance certificate or endorsement, nor the County's receipt of any other information from the Contractor, its insurance broker(s) and/or insurer(s), constitutes a waiver of any of the Insurance Requirements.

## **6. Laws and Regulations.**

6.1. Compliance with Laws. Contractor will comply with all federal, state, and local laws, rules, regulations, standards and Executive Orders.

6.2. Licensing. Contractor warrants that it is appropriately licensed to provide the services under this Contract and that its subcontractors will be appropriately licensed.

6.3. Choice of Law; Venue. The laws and regulations of the State of Arizona govern the rights and obligations of the parties under this Contract. Any action relating to this Contract must be filed and maintained in the appropriate court of the State of Arizona in Pima County.

7. **Non-Discrimination**. Contractor will comply with all provisions and requirements of Arizona Executive Order 2009-09, which is hereby incorporated into this Contract, including flow-down of all provisions and requirements to any subcontractors. During the performance of this Contract, Contractor will not discriminate against any employee, client or any other individual in any way because of that person's age, race, creed, color, religion, sex, disability or national origin.

8. **Authority to Contract**. Contractor warrants its right and power to enter into this Contract. If any court or administrative agency determines that County does not have authority to enter into this Contract, County will not be liable to Contractor or any third party by reason of such determination or by reason of this Contract.

9. **Full and Complete Performance**. The failure of either party to insist, in one or more instances, upon the other party's complete and satisfactory performance under this Contract, or to take any action based on the other party's failure to completely and satisfactorily perform, is not a waiver of that party's right to insist upon complete and satisfactory performance, or compliance with any other covenant or condition in this Contract, either in the past or in the

future. The acceptance by either party of sums less than may be due and owing it at any time is not an accord and satisfaction.

**10. Cancellation for Conflict of Interest.** This Contract is subject to cancellation for conflict of interest pursuant to A.R.S. § 38-511, the pertinent provisions of which are incorporated into this Contract by reference.

**11. Termination by County.**

11.1. Without Cause. County may terminate this Contract at any time, without cause, by serving a written notice upon Contractor at least 30 days before the effective date of the termination. In the event of such termination, County's only obligation to Contractor will be payment for services rendered prior to the date of termination.

11.2. With Cause. County may terminate this Contract at any time without advance notice and without further obligation to County when County finds Contractor to be in default of any provision of this Contract.

11.3. Non-Appropriation. Notwithstanding any other provision in this Contract, County may terminate this Contract if for any reason there are not sufficient appropriated and available monies for the purpose of maintaining County or other public entity obligations under this Contract. In the event of such termination, County will have no further obligation to Contractor, other than to pay for services rendered prior to termination.

**12. Notice.** Any notice required or permitted to be given under this Contract must be in writing and be served by personal delivery or by certified mail upon the other party as follows:

County:

Donald Gates, Business Operations  
Manager  
Pima County Health Department  
3950 S. Country Club Rd. Suite 200  
Tucson, AZ 85714  
(520)724-7843  
Donald.Gates@pima.gov

Contractor:

Carlos Rico, Chief Financial Officer  
  
El Rio Community Health Center  
839 W. Congress Street  
Tucson, AZ 85745  
(520) 670-3705  
CarlosR3@elrio.org

Contractor:

Lisa Ritter, Owner & Managing Partner  
Rescue Me Wellness, L.L.C.  
4601 E. 5<sup>th</sup> Street  
Tucson, AZ 85711  
(520) 300-7356  
lritter@rescuemewellness.com

**13. Remedies.** Either party may pursue any remedies provided by law for the breach of this Contract. No right or remedy is intended to be exclusive of any other right or remedy and each is cumulative and in addition to any other right or remedy existing at law or at equity or by virtue of this Contract.



- 14. Use of County Data.** Unless it receives County's prior written consent, Contractor: (a) shall not access, process, or otherwise use County Data other than as necessary to provide contracted services or products; and (b) shall not intentionally grant any third party access to County Data, including without limitation Contractor's other customers, except subcontractors that are subject to a reasonable nondisclosure agreement. Notwithstanding the foregoing, Contractor may disclose County Data as required by applicable law or by proper legal or governmental authority. Contractor shall give County prompt notice of any such legal or governmental demand and reasonably cooperate with County in any effort to seek a protective order or otherwise to contest such required disclosure, at County's expense. Upon termination or completion of the Contract, Contractor will, within 60 calendar days, either return all County Data to County or will destroy County Data and confirm destruction to County in writing. As between the parties, County retains ownership of County Data. "County Data" means data in electronic or paper form provided to Contractor by County, including without limitation personal identifying information as defined in A.R.S. § 13-2001(10).
- 15. Research.** No research activities, including academic, methodological or other, will be performed without the explicit authorization of the Pima County Health Department Director. This includes, among other elements, validation studies of alternative testing methods. Such authorization will only be considered following submission of a detailed research plan.
- 16. Policies, Procedures, Orders and Quality Assurance Documents.** CONTRACTOR will provide COUNTY with all standard operating procedures, policies and orders or other documents related to the fulfillment of duties identified in this contract. CONTRACTOR will provide COUNTY with updates to those policies, procedures, orders or other documents in a timely fashion and will not implement those changes until such time as COUNTY has reviewed and provided written or electronic approval. CONTRACTOR will adhere to the quality assurance requirements detailed in **Exhibit C – Quality Agreement**.
- 17. Health Insurance Portability and Accountability Act (HIPAA).** The parties acknowledge that the County is a hybrid covered entity as described in 45 C.F.R. §164.103 of 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 is required to comply with the provisions of the HIPAA Privacy and Security Rules with respect to safeguarding the privacy, confidentiality and security of protected health information. Contractor acknowledges that it may obtain protected health information, as defined in 45 C.F.R. §160.103, in the course of Contractor's performance under the terms of this Contract. Furthermore, Contractor acknowledges that County will utilize protected health information for research purposes, as defined in 45 C.F.R. § 164.501, and will obtain an authorization in compliance with 45 C.F.R. § 164.508, if required by the HIPAA Privacy and Security Rules. 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 D Business Associate Agreement** (7 pages) which is incorporated into this agreement, and further specifically agrees that:
- 17.1. Any protected health information that Contractor may obtain shall remain the sole property of the County; and
- 17.2. Contractor shall establish and maintain procedures and controls that are acceptable to County to assure that no protected 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

17.3. Contractor shall not remove any protected health information from County premises, if applicable; and

17.4. 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.

**18. Books and Records.** Contractor will keep and maintain proper and complete books, records and accounts, which will be open at all reasonable times for inspection and audit by duly authorized representatives of County. In addition, Contractor will retain all records relating to this Contract for at least five (5) years after its expiration or termination or, if later, until any related pending proceeding or litigation has concluded.

**19. Public Records.**

19.1. Disclosure. Pursuant to A.R.S. § 39-121 et seq., all documents related to this Contract, including, but not limited to, pricing schedules, product specifications, work plans, and any supporting documents, are public records. As such, those documents are subject to release and/or review by the general public upon request, including competitors.

19.2. Records Marked Confidential; Notice and Protective Order. If Contractor reasonably believes that some of its records contain proprietary, trade-secret or otherwise-confidential information, Contractor must prominently mark those records "CONFIDENTIAL" before submitting them to County. In the event a public-records request is submitted to County for records marked CONFIDENTIAL, County will notify Contractor of the request as soon as reasonably possible. County will release the records 10 business days after the date of that notice, unless Contractor has, within that period, secured an appropriate order from a court of competent jurisdiction in Arizona, enjoining the release of the records. County will not, under any circumstances, be responsible for securing such an order, nor will County be in any way financially responsible for any costs associated with securing such an order.

**20. Legal Arizona Workers Act Compliance.**

20.1. Compliance with Immigration Laws. Contractor hereby warrants that it will at all times during the term of this Contract comply with all federal immigration laws applicable to its employment of its employees, and with the requirements of A.R.S. § 23-214 (A) (together the "State and Federal Immigration Laws"). Contractor will further ensure that each subcontractor who performs any work for Contractor under this Contract likewise complies with the State and Federal Immigration Laws.

20.2. Books & Records. County has the right at any time to inspect the books and records of Contractor and any subcontractor in order to verify such party's compliance with the State and Federal Immigration Laws.

20.3. Remedies for Breach of Warranty. Any breach of Contractor's or any subcontractor's warranty of compliance with the State and Federal Immigration Laws, or of any other provision of this section, is a material breach of this Contract subjecting Contractor to penalties up to and including suspension or termination of this Contract. If the breach is by a subcontractor, and the subcontract is suspended or terminated as a result, Contractor will be required to take such steps as may be necessary to either self-perform the services that would have been provided under the subcontract or retain a replacement subcontractor, as soon as possible so as not to delay project completion. Any additional costs attributable directly or indirectly to such remedial action are the responsibility of Contractor.

20.4. Subcontractors. Contractor will advise each subcontractor of County's rights, and the subcontractor's obligations, under this Section 25 by including a provision in each subcontract substantially in the following form:

"Subcontractor hereby warrants that it will at all times during the term of this contract comply with all federal immigration laws applicable to Subcontractor's employees, and with the requirements of A.R.S. § 23-214 (A). Subcontractor further agrees that County may inspect the Subcontractor's books and records to insure that Subcontractor is in compliance with these requirements. Any breach of this paragraph by Subcontractor is a material breach of this contract subjecting Subcontractor to penalties up to and including suspension or termination of this contract."

**21. Written Orders.** County will order products or services under this Contract by issuing a Delivery Order (DO) document. Order documents will be furnished to Contractor via e-mail or telephone.

Contractor must not supply materials or services pursuant to the contract that are not documented or authorized by a Delivery Order (DO) at the time of provision. County accepts no responsibility for control of or payment for materials or services not documented by a County Delivery Order (DO).

Contractor will establish, monitor, and manage an effective contract administration process that assures compliance with all requirements of this Contract. In particular, Contractor will not provide goods or services other than those described in this Contract, in excess of the Maximum Payment Amount, or after the Term of the Contract has ended, without a Contract amendment properly executed and issued by County, as provided below. Any items provided in excess of that stated in this Contract are at Contractor's own risk.

**22. Counterparts.** The parties may execute the Contract that County awards pursuant to the solicitation in any number of counterparts, each counterpart is considered an original, and together such counterparts constitute one and the same instrument.

**23. Amendment.** The parties may modify, amend, alter or extend this Contract only by a written amendment signed by the parties.

**24. Entire Agreement.** This document constitutes the entire agreement between the parties pertaining to the subject matter it addresses, and this Contract supersedes all prior or contemporaneous agreements and understandings, oral or written.

This Contract will become effective when all parties have signed it. The effective date of the Contract will be the date this Contract is signed by the last party (as indicated by the date associated with that party's signature).

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IN WITNESS WHEREOF, the parties have approved this Cooperative Procurement Agreement and agree to be bound by the terms and conditions of the Contract on the dates written below.

**PIMA COUNTY**

**CONTRACTOR**

\_\_\_\_\_  
Chairman, Board of Supervisors

\_\_\_\_\_  
Authorized Officer Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name and Title

\_\_\_\_\_  
Date

**ATTEST**

\_\_\_\_\_  
Clerk of the Board

\_\_\_\_\_  
Date

**APPROVED AS TO FORM**

**APPROVED AS TO CONTENT**

  
\_\_\_\_\_  
Deputy County Attorney  
**Jonathan Pinkney**

  
\_\_\_\_\_  
Department Head

\_\_\_\_\_  
Print DCA Name

09/28/20  
\_\_\_\_\_  
Date

9/28/2020  
\_\_\_\_\_  
Date

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**PIMA COUNTY**

\_\_\_\_\_  
Chairman, Board of Supervisors

\_\_\_\_\_  
Date

**CONTRACTOR**

  
\_\_\_\_\_  
Authorized Officer Signature

Nancy Johnson CEO  
\_\_\_\_\_  
Printed Name and Title

9/29/2020  
\_\_\_\_\_  
Date

**ATTEST**

\_\_\_\_\_  
Clerk of the Board

\_\_\_\_\_  
Date

**APPROVED AS TO FORM**

  
\_\_\_\_\_  
Deputy County Attorney  
**Jonathan Pinkney**

\_\_\_\_\_  
Print DCA Name

9/28/2020  
\_\_\_\_\_  
Date

**APPROVED AS TO CONTENT**

\_\_\_\_\_  
Department Head

\_\_\_\_\_  
Date

This Contract will become effective when all parties have signed it. The effective date of the Contract will be the date this Contract is signed by the last party (as indicated by the date associated with that party's signature).

IN WITNESS WHEREOF, the parties have approved this Cooperative Procurement Agreement and agree to be bound by the terms and conditions of the Contract on the dates written below.

**PIMA COUNTY**

\_\_\_\_\_  
Chairman, Board of Supervisors

\_\_\_\_\_  
Date

**CONTRACTOR**

  
\_\_\_\_\_  
Authorized Officer Signature

Lisa Ritter, owner  
Printed Name and Title

09/30/2020  
Date

**ATTEST**

\_\_\_\_\_  
Clerk of the Board

\_\_\_\_\_  
Date

**APPROVED AS TO FORM**

  
\_\_\_\_\_  
Deputy County Attorney

**Jonathan Pinkney**

\_\_\_\_\_  
Print DCA Name

9/28/2020  
Date

**APPROVED AS TO CONTENT**

  
\_\_\_\_\_  
Department Head

09/28/20  
Date

## EXHIBIT A –Scope of Services (2 pages)

The scope of services from the City of Tucson solicitation is refined below, including updates and additions.

### PIMA COUNTY SCOPE OF SERVICE ADDITIONS

1. CONTRACTOR will provide RT-PCR COVID-19 testing services at a fixed location and/or remote locations as directed by Pima County;
  - a. All clinical services will be provided by appropriately trained and licensed CONTRACTOR staff at CONTRACTOR expense;
  - b. Services, including results notification, are to be available Sunday-Saturday in recognition that identification and communication of positive COVID-19 tests is most valuable when rapidly delivered to the individual being tested;
  - c. For services under this contract, CONTRACTOR may be designated as solely operating under fixed location or remote location by COUNTY;
2. If CONTRACTOR has the capacity to perform FDA approved antigen testing under this contract, COUNTY may elect to direct CONTRACTOR to perform antigen testing, RT-PCR, or both at specific times, locations or events. This direction is subject to change based on the needs of COUNTY and the individuals being tested;
3. For remote location testing, CONTRACTOR will provide all necessary equipment and supplies including but not limited to tent(s), table(s), forms, swabs, specimen bags, labels, registration and consent materials, etc.;
4. CONTRACTOR will document patient consent and waiver of HIPAA restrictions prior to collecting specimens from the patient;
5. CONTRACTOR will bill COUNTY for services rendered at COUNTY direction and will not seek payment, reimbursement or other funds from individuals tested under this contract;
  - a. Repeat testing without clinical justification is to be discouraged. CONTRACTOR and COUNTY will identify a mutually agreeable strategy to decrease incidence of unnecessary repeat testing;
6. CONTRACTOR will provide results via electronic portal to patients within 48 hours from specimen collection;
  - a. Compensation for test results delivered outside of the 48 hour window will be reduced by 25%;
  - b. Should the electronic portal be inaccessible for a period exceeding 24 hours, CONTRACTOR will, at their own expense, convey results to tested clients via an alternative means (phone, electronic communication, etc) and continue to do so until such time as the portal is again accessible. The means used to disseminate results must be in accordance with HIPAA guidelines, requiring proper consent from the patient prior to leaving messages or using electronic modes of communication.
7. CONTRACTOR will provide results to COUNTY daily in an aggregate electronic format acceptable to COUNTY. Sample is provided as **EXHIBIT A-1 Electronic Log Sample (2 pages)**;
8. CONTRACTOR will identify to the Pima County Health Department the clinical officer who will provide comprehensive clinical oversight of the CONTRACTOR's operations. This officer must be a licensed provider in the state of Arizona and be empowered to sign off

on CONTRACTOR orders, standard operating procedures and clinical regulatory documents.

- a. This officer will also serve as the primary clinical point of contact for Pima County and will coordinate with COUNTY medical officers as required.
9. CONTRACTOR will provide COUNTY with copies of all relevant standard operating procedures, standing orders, and operational policies and procedures prior to onset of testing under this contract;
  - a. CONTRACTOR will not administer COVID-19 tests to individuals under age 10 without prior approval from the Pima County Health Department. This approval will be issued only after review of CONTRACTOR policies, procedures and clinical orders related to testing of children. Once approval is granted, CONTRACTOR will be allowed to administer COVID-19 tests to clients under age 10 so long as those policies, procedures and orders are followed.
10. CONTRACTOR will not disclose protected health information to third parties except as required by law;
11. CONTRACTOR will not use test results or patient data collected under this contract for research purposes without the expressed consent of the Pima County Health Department Director;
12. CONTRACTOR will abide by the terms identified in EXHIBIT C – QUALITY ASSURANCE;
13. CONTRACTOR agrees that COUNTY reserves the right to observe and inspect any collection or testing sites with or without notice to CONTRACTOR.

**End of Exhibit A**



## Exhibit A-1 Electronic Log Sample (2 pages)

[illegible]

[illegible]

End of Exhibit A-1

## **EXHIBIT B – Compensation and Payment (1 page)**

Contractors should use all other available sources for compensation of testing. County will be responsible for authorized testing if it is not reimbursable by any other agency or source.

**Contractor:** El Rio Santa Cruz Neighborhood Health Center, Inc.

Item 1.	PCR Test at fixed site	\$140.00
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**Contractor:** Rescue Me Wellness, L.L.C.

Item 2.	PCR Test at mobile site	\$153.00
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CONTRACTOR will provide results via electronic portal to patients within 48 hours from specimen collection; compensation for test results delivered outside of the 48 hour window will be reduced by 25%.

CONTRACTOR will bill COUNTY for services rendered at COUNTY direction and will not seek payment, reimbursement or other funds from individuals tested under this contract.

Repeat testing without clinical justification is to be discouraged. CONTRACTOR and COUNTY will identify a mutually agreeable strategy to decrease incidence of unnecessary repeat testing.

**End of Exhibit B**

### Exhibit C – Quality Agreement (4 pages)

This exhibit comprises the 'Quality Agreement' and defines the roles and responsibilities of the Contractor and County related to analytical testing under this contract by, in accordance with current CLIA, CDC and any other applicable licensing, credentialing or safety requirements.

This Quality Agreement concerns the validation and transfer of test methods and samples, and the testing of samples of the contract data, processes and procedures to this Quality Agreement.

CONTRACTORS will test and handle samples, equipment, data, processes and procedures in compliance with the recognized pharmaceutical, lab, infection control and healthcare rules and relevant legal provisions. If COUNTY further wishes any special regulations or directives followed, that are not generally known and recognized under the above-mentioned regulations, COUNTY shall notify CONTRACTOR and the Parties will discuss in good faith how to proceed.

#### AUDITS AND INSPECTIONS

COUNTY has the right to inspect the CONTRACTORS facilities and the analyses of data, processes and procedures to ensure that the activities under this Quality Agreement are carried out in accordance with the health regulations.

Quarterly Reports will be sent to COUNTY with the following information (Example below):

Measure Definitions and Variation Studies EXAMPLES	Indicator (% or ratio) Relative to agreed upon defined threshold	Intervention (if outside threshold) Responsible Party Start Date	Post- Intervention Indicator (% or #)	Outcome Satisfactory or Unsatisfactory
Sample Gathering: Labeling Sample Collection Handling				
Processing to Result Time Interval				
Lab Process Errors (with sources)				
Result Validation Disparities				

CONTRACTORS further agrees that PIMA COUNTY HEALTH DEPARTMENT's affiliations, if previously coordinated and consented by PIMA COUNTY HEALTH DEPARTMENT, or competent authorities also have the right to inspect the facilities and the analyses of data, processes and procedures at the vendor's location. CONTRACTORS agrees to inform PIMA COUNTY HEALTH

DEPARTMENT in writing and without delay about planned inspections in advance and about problems found at inspections by authorities related to testing of PIMA COUNTY HEALTH DEPARTMENT's data, processes and procedures.

Audits will be performed on dates and times mutually agreed between the Parties, provided, however, that audits for investigational reason ('for cause audits') may be performed at any time during normal business hours.

#### **PROCEDURES AND DOCUMENTS**

CONTRACTORS is responsible for maintenance and update of its own SOPs to ensure that the processing and testing of the samples of data, processes and procedures is done in compliance with the FEDERAL, STATE AND/OR LOCAL Regulations. CONTRACTORS will make SOPs and related documents will available on demand by COUNTY.

#### **CHANGE MANAGEMENT**

Changes are variations to this Quality Agreement, and to any activity hereunder, relevant to the regulatory status of data, processes and procedures. Any intended major change must be submitted to COUNTY in writing and accepted by both Parties. Change approval by COUNTY is necessary prior to implementation.

#### **TEST SAMPLES, STORAGE**

CONTRACTORS will ensure that the samples to be tested are prepared and unambiguously labelled (including the batch number) and that the necessary information (laboratory order per sample or cluster of samples, storage conditions, safety handling requirement/MSDS, etc) is recorded and available. CONTRACTORS is responsible to store samples received at ambient temperature or as specified in the analytical order accompanying the sample.

#### **INSTRUMENT CALIBRATION AND VALIDATION**

Quality controls are to be completed in compliance with the Federal, State And/Or Local Regulations, using qualified, calibrated equipment and machines as well as validated testing methods. Data, processes and procedures and specific validation of testing methods is to be provided quarterly by CONTRACTORS to COUNTY by the 15<sup>th</sup> of the month following each quarter.

#### **REAGENTS, MATERIALS**

CONTRACTOR is liable for the regular quality of the reagents/materials used.

#### **PERSONNEL**

During the period of this contract, CONTRACTORS ensures that suitable rooms or settings, equipment and qualified personnel are available to carry out the corresponding activities and can provide substantiating documentation upon request. CONTRACTORS shall inform PIMA COUNTY HEALTH DEPARTMENT without delay if essential changes happen in their management or essential operational staff.

#### **REVIEW AND STORAGE OF RAW DATA AND REPORTS**

All raw data acquired by CONTRACTORS for COUNTY and the subsequent calculations of results shall be reviewed, dated and initialed by a second analyst at vendor's company and

assessed for conformity. The summary reports are to be authorized by CONTRACTOR official prior to quarterly submission to COUNTY. CONTRACTORS shall keep the documentation (including but not limited to raw data, calculations, testing instructions and final reports) for at least 10 years after issue of the final report. In addition, all raw data related to analytical development, including but not limited to any raw data from method validation, will be archived by CONTRACTORS over the life cycle of the concerned data, processes and procedures.

CONTRACTORS must submit a written request for COUNTY authorization prior to the disposal of any raw data related to COUNTY's orders and data, processes and procedures. At COUNTY's sole discretion it will authorize if such raw data shall be disposed of by CONTRACTORS or have to be transferred to COUNTY. In the case of closure of the business by CONTRACTORS or expiry of its authority approval the documentation has to be transferred to COUNTY.

**DEVIATIONS FROM TESTING INSTRUCTIONS AND OOS/OOE RESULTS** If not otherwise agreed to, Out Of Specification (OOS) and Out of Trend results and/or unplanned deviations shall be handled according to the CONTRACTORS SOP and shall be reported to COUNTY within 3 business days. Prior to effecting any planned deviations from the agreed testing instructions CONTRACTORS will notify COUNTY. Subsequently CONTRACTORS shall complete a deviation report including an explanation of the reasons for the deviation and transmit this report to COUNTY together with the final report for affected sample or data, processes and procedures batch.

#### **16. FORMAT OF THE FINAL REPORTS**

For each lab batch tested, CONTRACTORS will provide COUNTY with an aggregate report detailing the batch testing results in a mutually agreeable manner. In addition, CONTRACTORS will provide Certificates of Compliance (CoC) with regard to FEDERAL, STATE AND/OR LOCAL bodies and registration compliance for certain labs, processes, procedures equipment and batches tested, if specifically requested by COUNTY.

Additional information (including raw data) may be required by COUNTY and shall be provided by CONTRACTORS upon request; especially for investigations in case of complaints and/or recall.

#### **RESULT TRANSFER**

CONTRACTORS will complete the agreed tests without delay (within 48 hours for COVID testing or 2 business days for other testing unless otherwise specified in the contract), and transfer the final report (Aggregate or Analytical Report) by e-mail to the COUNTY and electronically to the State within the expected timeframes as outlined by regulation. COUNTY's due dates for receipt of the final report (Aggregate or Analytical Report) are daily for testing and quarterly for QA/QI/QC. In case of delay, CONTRACTORS immediately shall inform COUNTY about reasons and time line. If no due date determined by agreed upon processing time is expressly specified in the original contract time limits will be determined and the contract amended.

#### **FINAL PROVISIONS**

This Quality Agreement shall become effective and binding upon the date of the final signature and shall remain in effect until 2 years after the last delivery of data, processes and procedures

by COUNTY to CONTRACTORS unless the Parties specifically agree in writing an extension of the Quality Agreement.

If individual provisions of this Quality Agreement are rendered void or unenforceable, they shall be replaced by the legally permissible interpretation that most closely approaches the original intent and they shall not be construed to render any other provision of this Quality Agreement either void or unenforceable.

**End of Exhibit C**

## **Exhibit D Business Associate Agreement (7 pages)**

WHEREAS, Pima County, on behalf of the Pima County Health Department ("Covered Entity"), and Paradigm Laboratories, LLC dba PD Diagnostics, LLC ("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.

**End of Exhibit D**