



SEDGWICK COUNTY, KANSAS
DIVISION OF FINANCE DEPARTMENT
Purchasing Department

100 N. Broadway, Suite 610~ Wichita, KS 67203
Phone: 316 660-7255 Fax: 316 660-1839

[https://www.sedgwickcounty.org/finance/purchasing/
requests-for-bid-and-proposal/](https://www.sedgwickcounty.org/finance/purchasing/requests-for-bid-and-proposal/)

REQUEST FOR PROPOSAL
RFP #22-0043
LAB SERVICES FOR SARS-CoV-2 TESTING

June 13, 2022

Sedgwick County, Kansas (hereinafter referred to as “county”) is seeking a firm or firms to provide Lab Services for SARS-CoV-2 Testing. If your firm is interested in submitting a response, please do so in accordance with the instructions contained within the attached Request for Proposal. Responses are due no later than 1:45 pm CDT, July 12, 2022.

All contact concerning this solicitation shall be made through the Purchasing Department. Bidders shall not contact county employees, department heads, using agencies, evaluation committee members or elected officials with questions or any other concerns about the solicitation. Questions, clarifications and concerns shall be submitted to the Purchasing Department in writing. Failure to comply with these guidelines may disqualify the Bidder’s response.

Sincerely,

A handwritten signature in cursive script, appearing to read "Theresa Rhodes".

Theresa Rhodes
Purchasing Agent

TR/ks

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I. About this Document

This document is a Request for Proposal. It differs from a Request for Bid or Quotation in that the county is seeking a solution, as described on the cover page and in the following Background Information section, not a bid or quotation meeting firm specifications for the lowest price. As such, the lowest price proposed will not guarantee an award recommendation. As defined in Charter Resolution No. 68, Competitive Sealed Proposals will be evaluated based upon criteria formulated around the most important features of the product(s) and/or service(s), of which quality, testing, references, service, availability or capability, may be overriding factors, and price may not be determinative in the issuance of a contract or award. The proposal evaluation criteria should be viewed as standards that measure how well a vendor's approach meets the desired requirements and needs of the county. Criteria that will be used and considered in evaluation for award are set forth in this document. The county will thoroughly review all proposals received. The county will also utilize its best judgment when determining whether to schedule a pre-proposal conference, before proposals are accepted, or meetings with vendors, after receipt of all proposals. A Purchase Order/Contract will be awarded to a qualified vendor submitting the best proposal. **Sedgwick County reserves the right to select, and subsequently recommend for award, the proposed service(s) and/or product(s) which best meets its required needs, quality levels and budget constraints.**

The nature of this work is for a public entity and will require the expenditure of public funds and/or use of public facilities, therefore the successful proposer will understand that portions (potentially all) of their proposal may become public record at any time after receipt of proposals. Proposal responses, purchase orders and final contracts are subject to public disclosure after award. All confidential or proprietary information should be clearly denoted in proposal responses and responders should understand this information will be considered prior to release, however no guarantee is made that information will be withheld from public view.

II. Background

Sedgwick County, located in south-central Kansas, is one of the most populous of Kansas' 105 counties with a population estimated at more than 514,000 persons. It is the sixteenth largest in area, with 1,008 square miles, and reportedly has the second highest per capita wealth among Kansas' counties. Organizationally, the county is a Commission/Manager entity, employs nearly 2,500 persons, and hosts or provides a full range of municipal services, e.g. – public safety, public works, criminal justice, recreation, entertainment, cultural, human/social, and education.

SARS-CoV-2 is the virus that causes COVID-19 disease. The Sedgwick County Health Department (SCHD) laboratory can process internally up to 400 respiratory samples for SARS-CoV-2 testing per week. Beyond that, if there is an increased demand for testing, other laboratory services will be needed.

III. Project Objectives

Sedgwick County, Kansas (hereinafter referred to as "county") is seeking a firm or firms to provide Lab Services for SARS-CoV-2 testing. The following objectives have been identified for this contract:

1. Acquire lab services for SARS-CoV-2 testing meeting the parameters, conditions and mandatory requirements presented in the document.
2. Establish contract pricing with the vendor that has the best proven "track-record" in performance, service and customer satisfaction.
3. Acquire lab services for SARS-CoV-2 testing with the most advantageous overall cost to the county, including factors such as specimen transport, results reporting, and specimen processing costs.

IV. Submittals

Carefully review this Request for Proposal. It provides specific technical information necessary to aid participating firms in formulating a thorough response. Should you elect to participate, submit via email to purchasing@sedgwick.gov

SUBMITTALS are due **NO LATER THAN 1:45 pm CDT, TUESDAY, July 12, 2022**. Late or incomplete responses will not be accepted and will not receive consideration for final award. Vendor is responsible for verifying that their proposal has been received by Sedgwick County Purchasing Department.

Proposal responses will be acknowledged and read into record at Bid Opening, which will occur at 2:00 pm CDT on the due date. No information other than the respondent's name will be disclosed at Bid Opening. If you would like to listen in as these are read into the record, please dial our Meet Me line @ (316) 660-7271 at 2:00 pm.

V. Scope of Work

These are items needed for effective Lab Services:

- Lab will process between 400 – 5,000 samples per week for SARS-CoV-2 testing and ability to rapidly adjust to fluctuating levels of specimens for processing. SCHD will notify of the need for laboratory services no less than two (2) business days in advance.
- Lab will provide multiplex testing that includes SARS-CoV-2 and influenza A and B.
- Lab will provide confirmatory nucleic acid amplification testing (such as PCR) for SARS-CoV-2.
- Lab will provide 24 hour turnaround time for results - from sample collection to patient receiving results. If specimens are collected on Saturday or Sunday, turnaround time for patients to receive results will be by six (6) pm on Monday.
- Lab will be responsible for picking up specimens for testing.
- Lab will be responsible for reporting to applicable federal and state health authorities regarding test results.
- Lab will provide specimen kits for collection.
- Lab will provide shipping containers with proper biohazard labeling.
- Lab will connect electronically to the Kansas Department of Health and Environment/Kansas Health and Environmental Laboratories for reporting.
- Lab will report invalid samples or processing to SCHD within one (1) day.
- Lab runs samples daily Monday through Friday and can also run on Saturday (upon request given five (5) business days in advance).
- Lab will provide electronic patient registration system for patients to pre-register prior to arriving at the testing site.
- Lab will provide access to test results for all patients to SCHD.
- Lab will provide to SCHD the ability to electronically or manually batch upload patient results to SCHD electronic health record system, Athena.
- Lab staff will be available for technical issue resolution within one business day for non-urgent and within one (1) hour for urgent issues.
- Lab staff will attend planning and after action meetings with SCHD with five (5) business day notice if non-urgent and within one (1) business day if urgent.

VI. Sedgwick County's Responsibilities

- Provide information, as legally allowed, in possession of the county, which relates to the county's requirements or which is relevant to this project.
- Designate a person to act as the County Contract Manager with respect to the work to be performed under this contract.

VII. Proposal Terms

A. Questions and Contact Information

Any questions regarding this document must be submitted in writing to Theresa Rhodes at Theresa.Rhodes@sedgwick.gov by 5:00 pm CDT, June 20, 2022. Any questions of a substantive nature will be answered in written form as an addendum and posted on the purchasing website at <https://www.sedgwickcounty.org/finance/purchasing/requests-for-bid-and-proposal/> under the Documents column associated with this RFP number by 5:00 pm CDT, June 24, 2022. Firms are responsible for checking the website and acknowledging any addenda on their proposal response form.

B. Minimum Firm Qualifications

This section lists the criteria to be considered in evaluating the ability of firms interested in providing the service(s) and/or product(s) specified in this Request for Proposal. Firms must meet or exceed these qualifications to be considered for award. Any exceptions to the requirements listed should be clearly detailed in proposer's response. Proposers shall:

1. Have a minimum of one (1) year of experience in providing services similar to those specified in this RFP.
2. Have an understanding of industry standards and best practices.
3. Have experience in managing projects of comparable size and complexity to that being proposed.
4. Have knowledge of and comply with all currently applicable, and as they become enacted during the contract term, federal, state and local laws, statutes, ordinances, rules and regulations. All laws of the State of Kansas, including CLIA certification, HIPAA compliance, and compliance with laboratory reporting to the Kansas Department of Health and Environment, whether substantive or procedural, shall apply to the contract, and all statutory, charter, and ordinance provisions that are applicable to public contracts in the county shall be followed with respect to the contract.
5. Prior work with municipal and county government experience is desired, however, the county will make the final determination based on responses received and the evaluation process.
6. Have the capacity to acquire all bonds, escrows or insurances as outlined in the terms of this RFP.
7. Provide laboratory supervision (as required by CLIA) and quality control procedures
8. Provide timely responses for inquiries regarding specimens and/or testing by SCHD.
9. Have appropriate material, equipment and labor to perform specified services.

C. Evaluation Criteria

The selection process will be based on the responses to this RFP. County staff will judge each response as determined by the scoring criteria below. Purchasing staff are not a part of the evaluation committee.

Component	Points
A. Responses to Operations Form	30
B. Ability to meet or exceed scope of work	25
C. Qualifications and expertise	25
D. References	10
E. Pricing*	10
Total Points	100

Assume the following cost proposals (**examples only**)

- A. \$50,000.00
- B. \$38,000.00
- C. \$49,000.00

Company B with a total price of \$38,000.00 is the low offer. Take the low offer and divide each of the other offers into the low offer to calculate a percentage. This percentage is then multiplied by the number of points available for the cost. In this case, 10 points are allocated to cost.

- A. \$38,000.00 divided by \$50,000.00 =.76 .76*10 7.6 points
- B. \$38,000.00 divided by \$38,000.00 =1.00 1.00*10 10 points
- C. \$38,000.00 divided by \$49,000.00=.77 .77*10 7.7 points

Any final negotiations for services, terms and conditions will be based, in part, on the firm’s method of providing the service and the fee schedule achieved through discussions and agreement with the county’s review committee. The county is under no obligation to accept the lowest priced proposal and reserves the right to further negotiate services and costs that are proposed. The county also reserves the sole right to recommend for award the proposal and plan that it deems to be in its best interest.

The county reserves the right to reject all proposals. All proposals, including supporting documentation shall become the property of Sedgwick County. All costs incurred in the preparation of this proposal shall be the responsibility of the firm making the proposals. Sedgwick County reserves the right to select, and subsequently recommend for award, the proposed service which best meets its required needs, quality levels and budget constraints.

D. [Request for Proposal Timeline](#)

The following dates are provided for information purposes and are subject to change without notice. Contact the Purchasing Department at (316) 660-7255 to confirm any and all dates.

Distribution of Request for Proposal to interested parties	June 13, 2022
Questions and clarifications submitted in writing by 5:00 pm CDT	June 20, 2022
Addendum Issued by 5:00 pm CDT	June 24, 2022
Sealed Proposal due before 1:45 pm CDT	July 12, 2022
Evaluation Period	July 12, 2022 – July 22, 2022
Board of Bids and Contracts Recommendation	July 28, 2022
Board of County Commission Award	August 3, 2022

E. [Contract Period and Payment Terms](#)

A contractual period will begin following Board of County Commissioners (BoCC) approval of the successful firm(s) and continue for a period of two (2) years with two (2) one (1) year options to renew.

County may cancel its obligations herein upon thirty-day (30) prior written notice to the other party. It is understood that funding may cease or be reduced at any time, and in the event that adequate funds are not available to meet the obligations hereunder, either party reserves the right to terminate this agreement upon thirty (30) days prior written notice to the other. Payment will be remitted following receipt of monthly detailed invoice.

Payment and Invoice Provisions

https://www.sedgwickcounty.org/media/39239/payment_and_invoice_provisions.pdf

F. [Insurance Requirements](#)

Liability insurance coverage indicated below must be considered as primary and not as excess insurance. If required, contractor’s professional liability/errors and omissions insurance shall (i) have a policy retroactive date prior to the date any professional services are provided for this project, and (ii) be maintained for a minimum of three (3) years past completion of the project. Contractor shall furnish a certificate evidencing such coverage, with county listed as an additional insured including both ongoing and completed operations, except for professional liability, workers’ compensation and employer’s liability. **Certificate shall be provided prior to award of contract.** Certificate shall remain in force during the duration of the project/services and will not be canceled, reduced, modified, limited, or restricted until thirty (30) days after county receives written notice of such change. All insurance must be with an insurance company with a minimum BEST rating of A-VIII and licensed to do business in the State of Kansas (**must be acknowledged on the bid/proposal response form**).

NOTE: If any insurance is subject to a deductible or self-insured retention, written disclosure must be included in your proposal response and also be noted on the certificate of insurance.

It is the responsibility of contractor to require that any and all approved subcontractors meet the minimum insurance requirements.

Workers' Compensation:	
Applicable coverage per State Statutes	
Employer's Liability Insurance:	\$500,000.00
Commercial General Liability Insurance (on form CG 00 01 04 13 or its equivalent):	
Each Occurrence	\$1,000,000.00
General Aggregate, per project	\$2,000,000.00
Personal Injury	\$1,000,000.00
Products and Completed Operations Aggregate	\$2,000,000.00
Automobile Liability:	
Combined single limit	\$500,000.00
Umbrella Liability:	
Following form for both the general liability and automobile	
<input checked="" type="checkbox"/> Required / <input type="checkbox"/> Not Required	
Each Claim	\$1,000,000.00
Aggregate	\$1,000,000.00
Professional Liability/ Errors & Omissions Insurance:	
<input checked="" type="checkbox"/> Required / <input type="checkbox"/> Not Required	
Each Claim	\$1,000,000.00
Aggregate	\$1,000,000.00
Pollution Liability Insurance:	
<input type="checkbox"/> Required / <input checked="" type="checkbox"/> Not Required	
Each Claim	\$1,000,000.00
Aggregate	\$1,000,000.00

Special Risks or Circumstances:

Entity reserves the right to modify, by written contract, these requirements, including limits, based on the nature of the risk, prior experience, insurer, coverage, or other special circumstances.

IF CONTRACTOR IS PROVIDING CONSTRUCTION SERVICES:

In addition to the above coverages, contractor shall also provide the following:

Builder's Risk Insurance:	In the amount of the initial Contract Sum, plus the value of subsequent modifications and cost of materials supplied and installed by others, comprising the total value for the entire Project on a replacement cost basis without optional deductibles. Entity, contractor, and all Subcontractors shall be included as named insured's.
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G. [Indemnification](#)

To the fullest extent of the law, the provider, its subcontractor, agents, servants, officers or employees shall indemnify and hold harmless Sedgwick County, including, but not limited to, its elected and appointed officials, officers, employees and agents, from any and all claims brought by any person or entity whatsoever, arising from any act, error, or omission of the provider during the provider's performance of the agreement or any other agreements of the provider entered into by reason thereof. The provider shall indemnify and defend Sedgwick County, including, but not limited to, its elected and appointed officials, officers, employees and agents, with respect to any claim arising, or alleged to have arisen from negligence, and/or willful, wanton or reckless acts or omissions of the provider, its subcontractor, agents, servants, officers, or employees and any and all losses or liabilities resulting from any such claims, including, but not limited to, damage awards, costs and reasonable attorney's fees. This indemnification shall not be affected by any other portions of the agreement relating to insurance requirements. The provider agrees that it will procure and keep in force at all times at its own expense insurance in accordance with these specifications.

H. [Confidential Matters and Data Ownership](#)

The successful proposer agrees all data, records and information, which the proposer, its agents and employees, which is the subject of this proposal, obtain access, remains at all times exclusively the property of Sedgwick County. The successful proposer agrees all such data, records, plans and information constitutes at all times proprietary information of Sedgwick County. The successful proposer agrees that it will not disclose, provide, or make available any of such proprietary information in any form to any person or entity. The patient data is considered protected health information and is covered under HIPAA and applicable state statutes and regulations on infectious disease reporting to the State of Kansas. In addition, the successful proposer agrees it will not use any names or addresses contained in such data, records, plans and information for the purpose of selling or offering for sale any property or service to any person or entity who resides at any address in such data. In addition, the successful proposer agrees it will not sell, give or otherwise make available to any person or entity any names or addresses contained in or derived from such data, records and information for the purpose of allowing such person to sell or offer for sale any property or service to any person or entity named in such data. Successful proposer agrees it will take all reasonable steps and the same protective precautions to protect Sedgwick County's proprietary information from disclosure to third parties as with successful proposer's own proprietary and confidential information. Proposer agrees that all data, regardless of the form that is generated as a result of this Request for Proposal is the property of Sedgwick County.

I. [Proposal Conditions](#)

<https://www.sedgwickcounty.org/media/31338/proposal-terms-conditions.pdf>

General Contract Provisions

<https://www.sedgwickcounty.org/media/31337/general-contractual-provisions.pdf>

Mandatory Contract Provisions

<https://www.sedgwickcounty.org/media/31336/mandatory-contractual-provisions.pdf>

Independent Contractor

<https://www.sedgwickcounty.org/media/54780/independent-contractor-addendum.pdf>

Sample Contract

<https://www.sedgwickcounty.org/media/39236/sample-contract.pdf>

Federal Certifications Addendum Sedgwick County

<https://www.sedgwickcounty.org/media/59719/federal-certifications-addendum-updated-for-changes-to-ug-11-12-2020-no-signature-line.pdf>

Suspension and Debarment

<https://www.sedgwickcounty.org/finance/purchasing/suspension-and-debarment/>

ARPA Exhibits F, G and H

<https://www.sedgwickcounty.org/media/61318/arpa-exhibits-f-h.pdf>

Appendix C - Mandatory ARPA Contractual Provisions

<https://www.sedgwickcounty.org/media/61409/appendix-c-mandatory-arpa-contractual-provisions.pdf>

VIII. Required Response Content

All proposal submissions shall include the following:

1. Firm profile: the name of the firm, address, telephone number(s), contact person, year the firm was established, and the names of the principals of the firm.
2. The firm's relevant experience, notably experience working with government agencies.
3. At minimum, three (3) professional references, besides Sedgwick County, with email addresses, telephone numbers, and contact persons where work has been completed within the last three (3) years.
4. Completed Scope of Work Checklist.
5. Completed Operations Form.
6. Submission of CLIA Certification and statement of laboratory reporting to Kansas Department of Health and Environment compliance with state regulation.
7. A disclosure of any personal or financial interest in any properties in the project area, or any real or potential conflicts of interest with members of the Sedgwick County Board of County Commissioners or county staff.
8. A description of the type of assistance that will be sought from county staff, including assistance required from the county to lessen the costs of this project.
9. Proof of insurance meeting minimum insurance requirements as designated herein.
10. Those responses that do not include all required forms/items may be deemed non-responsive.

IX. Response Form

**REQUEST FOR PROPOSAL
RFP #22-0043
LAB SERVICES FOR SARS-CoV-2 Testing**

The undersigned, on behalf of the proposer, certifies that: (1) this offer is made without previous understanding, agreement or connection with any person, firm, or corporation submitting a proposal on the same project; (2) is in all respects fair and without collusion or fraud; (3) the person whose signature appears below is legally empowered to bind the firm in whose name the proposer is entered; (4) they have read the complete Request for Proposal and understands all provisions; (5) if accepted by the county, this proposal is guaranteed as written and amended and will be implemented as stated; and (6) mistakes in writing of the submitted proposal will be their responsibility.

NAME _____

DBA/SAME _____

CONTACT _____

ADDRESS _____ CITY/STATE _____ ZIP _____

PHONE _____ FAX _____ HOURS _____

STATE OF INCORPORATION or ORGANIZATION _____

WEBSITE ADDRESS _____ EMAIL _____

NUMBER OF LOCATIONS _____ NUMBER OF PERSONS EMPLOYED _____

TYPE OF ORGANIZATION: Public Corporation _____ Private Corporation _____ Sole Proprietorship _____

Partnership _____ Other (Describe): _____

BUSINESS MODEL: Small Business _____ Manufacturer _____ Distributor _____ Retail _____

Dealer _____ Other (Describe): _____

Not a Minority-Owned Business: _____ Minority-Owned Business: _____ (Specify Below)

____ African American (05) ____ Asian Pacific (10) ____ Subcontinent Asian (15) ____ Hispanic (20)

____ Native American (25) ____ Other (30) - Please specify _____

Not a Woman-Owned Business: _____ Woman-Owned Business: _____ (Specify Below)

____ Not Minority -Woman Owned (50) ____ African American-Woman Owned (55) ____ Asian Pacific-Woman Owned (60)

____ Subcontinent Asian-Woman Owned (65) ____ Hispanic Woman Owned (70) ____ Native American-Woman Owned (75)

____ Other – Woman Owned (80) – Please specify _____

ARE YOU REGISTERED TO DO BUSINESS IN THE STATE OF KS: ____ Yes ____ No

UEI (UNIQUE ENTITY IDENTIFIER) NO. _____

INSURANCE REGISTERED IN THE STATE OF KS WITH MINIMUM BEST RATING OF A-VIII: ____ Yes ____ No

ACKNOWLEDGE RECEIPT OF ADDENDA: All addendum(s) are posted to our RFB/RFP web page and it is the vendor's responsibility to check and confirm all addendum(s) related to this document by going to www.sedgwickcounty.org/finance/purchasing.asp.

NO. _____, DATED _____; NO. _____, DATED _____; NO. _____, DATED _____

In submitting a proposal, vendor acknowledges all requirements, terms, conditions, and sections of this document. Proposal submission format should be by order in which sections are listed throughout the document. All minimum and general requirements should be specifically addressed and detailed in proposer's response. **Exceptions to any part of this document should be clearly delineated and detailed.**

Signature _____ Title _____

Print Name _____ Dated _____

Scope of Work Checklist

Item	Respond "Yes" or "No"
Lab will process between 400 – 5,000 samples per week for SARS-CoV-2 testing and ability to rapidly adjust to fluctuating levels of specimens for processing. SCHD will notify of the need for laboratory services no less than two (2) business days in advance.	
Lab will provide multiplex testing that includes SARS-CoV-2 and influenza A and B.	
Lab will provide confirmatory nucleic acid amplification testing (such as PCR) for SARS-CoV-2.	
Lab will provide 24 hour turnaround time for results - from sample collection to patient receiving result. If specimens are collected on Saturday or Sunday, turnaround time for patients to receive results will be by 6:00 pm on Monday.	
Lab will be responsible for picking up specimens for testing.	
Lab will be responsible for reporting to applicable federal and state health authorities regarding test results.	
Lab will provide specimen kits for collection.	
Lab will provide shipping containers with proper biohazard labeling.	
Lab will connect electronically to the Kansas Department of Health and Environment/Kansas Health and Environmental Laboratories for reporting.	
Lab will report invalid samples or processing to SCHD within one (1) day.	
Lab runs samples daily Monday through Friday and can also run on Saturday (upon request given five (5) business days in advance).	
Lab will provide electronic patient registration system for patients to pre-register prior to arriving at the testing site.	
Lab will provide access to test results for all patients to SCHD.	
Lab will provide to SCHD the ability to electronically or manually batch upload patient results to SCHD electronic health record system, Athena.	
Lab staff will be available for technical issue resolution within one business day for non-urgent and within one (1) hour for urgent issues.	
Lab staff will attend planning and after action meetings with SCHD with five (5) business day notice if non-urgent and within one (1) business day if urgent.	

X. Operations Form

Submission of Operations Information

Hours of Operation (days and time):

Hours of Sample Collection (days and time):

Years in Business as a Laboratory:

Specimen Types Accepted for COVID Testing:

Testing Methods/Methodologies:

Average Turnaround Time of Results (from sample collection to patient receiving results):

Maximum Capacity/Throughput:

Weekly Cost Estimates:

Number of Tests per Week	Cost
400	
1,000	
2,500	
5,000	

HIPAA RULES

BUSINESS ASSOCIATE ADDENDUM

DEFINITIONS

1.1 The following terms used in this Agreement shall have the same meaning as those terms in the HIPAA Rules: Breach, Data Aggregation, Designated Record Set, Disclosure, Health Care Operations, Individual, Minimum Necessary, Notice of Privacy Practices, Protected Health Information, Required By Law, Secretary, Security Incident, Subcontractor, Unsecured Protected Health Information, and Use.

Specific definitions:

(a) Business Associate. “Business Associate” shall generally have the same meaning as the term “business associate” at 45 CFR 160.103.

(b) Covered Entity. “Covered Entity” shall generally have the same meaning as the term “covered entity” at 45 CFR 160.103, and in reference to the party to this agreement, shall mean Sedgwick County.

(c) HIPAA Rules. HIPAA Rules” shall mean the Privacy, Security, Breach Notification, and Enforcement Rules at 45 CFR Part 160 and Part 164.

OBLIGATIONS AND ACTIVITIES OF BUSINESS ASSOCIATE

Business Associate agrees to:

2.1 Not Use or Disclose Protected Health Information other than as permitted or required by the Agreement or as Required By Law;

2.2 Use appropriate safeguards and comply with Subpart C of 45 CFR Part 164 with respect to electronic Protected Health Information, to prevent Use or Disclosure of Protected Health Information other than as provided for by this Agreement;

2.3 report to covered entity any Use or Disclosure of Protected Health Information not provided for by the Agreement of which it becomes aware, including Breaches of Unsecured Protected Health Information as required at 45 CFR 164.410, and any Security Incident of which it becomes aware, as further provided for in Par. 12.1, *et seq.*;

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

2.5 in accordance with 45 CFR 164.502(e)(1)(ii) and 164.308(b)(2), if applicable, ensure that any Subcontractors that create, receive, maintain, or transmit Protected Health Information on behalf of the Business Associate agree to the same restrictions, conditions, and requirements that apply to the Business Associate with respect to such information;

2.6 make available Protected Health Information in a Designated Record Set to the Covered Entity as necessary to satisfy Covered Entity’s obligations under 45 CFR 164.524;

2.7 make any amendment(s) to Protected Health Information in a Designated Record Set as directed or agreed to by the Covered Entity pursuant to 45 CFR 164.526 or take other measures as necessary to satisfy Covered Entity’s obligations under 45 CFR 164.526;

2.8 make its internal practices, books, and records available to the Secretary for purposes of determining compliance with the HIPAA Rules; and

2.9 maintain and make available the information required to provide an accounting of Disclosures to the Covered Entity as necessary to satisfy covered entity's obligations under 45 CFR 164.528.

PERMITTED USES AND DISCLOSURES BY ASSOCIATE

3.1 Except as otherwise limited in this Agreement, Business Associate may only Use or Disclose Protected Health Information on behalf of, or to provide services to, Covered Entity for the purposes of the contractual relationship, if such Use or Disclosure of Protected Health Information would not violate the Privacy Rule if done by Covered Entity or the Minimum Necessary policies and procedures of the Covered Entity.

SPECIFIC USE AND DISCLOSURE PROVISIONS

4.1 Except as otherwise limited in this Agreement, Business Associate may Use Protected Health Information for the proper management and administration of the Business Associate or to carry out the contractual or legal responsibilities of the Business Associate.

4.2 Business Associate may Use or Disclose Protected Health Information as Required By Law.

4.3 Business Associate agrees to make Uses and Disclosures and requests for Protected Health Information consistent with Covered Entity's Minimum Necessary policies and procedures.

4.4 Business Associate may Disclose Protected Health Information for the proper management and administration of Business Associate or to carry out the legal responsibilities of the Business Associate, provided the Disclosures are Required By Law, or Business Associate obtains reasonable assurances from the person to whom the information is disclosed that the information will remain confidential and Used or further Disclosed only as Required By Law or for the purposes for which it was Disclosed to the person, and the person notifies Business Associate of any instances of which it is aware in which the confidentiality of the information has been Breached.

4.5 Business Associate may provide Data Aggregation services relating to the Health Care Operations of the covered entity.

4.6 Business Associate may Use Protected Health Information to report violations of law to appropriate Federal and State authorities, consistent with § 164.502(j)(1).

OBLIGATIONS OF COVERED ENTITY

5.1 Covered Entity shall notify Business Associate of any limitation(s) in its Notice of Privacy Practices of Covered Entity in accordance with 45 CFR § 164.520, to the extent that such limitation may affect Business Associate's Use or Disclosure of Protected Health Information.

5.2 Covered Entity shall notify Business Associate of any changes in, or revocation of, permission by Individual to Use or Disclose Protected Health Information, to the extent that such changes may affect Business Associate's Use or Disclosure of Protected Health Information.

5.3 Covered Entity shall notify Business Associate of any restriction to the Use or Disclosure of Protected Health Information that Covered Entity has agreed to in accordance with 45 CFR § 164.522, to the extent that such restriction may affect Business Associate's Use or Disclosure of Protected Health Information.

PERMISSIBLE REQUESTS BY COVERED ENTITY

6.1 Covered Entity shall not request Business Associate to Use or Disclose Protected Health Information in any manner that would not be permissible under Subpart E of 45 CFR Part 164 if done by Covered Entity. If necessary in order to meet the Business Associate's obligations under the Agreement, the Business Associate may Use or Disclose Protected Health Information for Data Aggregation, management and administrative activities, or contractual or legal responsibilities of Business Associate.

TERM

7.1 **Term.** The Agreement shall be effective as of date of execution of the Agreement by the parties, and shall terminate when all of the Protected Health Information provided by Covered Entity to Business Associate, or created or received by Business Associate on behalf of Covered Entity, has been returned to Covered Entity or, at Covered Entity's option, is destroyed, or, if it is infeasible to destroy Protected Health Information, the protections are extended to such information, in accordance with the termination provisions in this Agreement.

MISCELLANEOUS

8.1 A reference in this Agreement to a section in the HIPAA Rules means the section as in effect or as amended.

8.2 The Parties agree to take such action as is necessary to amend this Agreement from time to time as is necessary for Covered Entity to comply with the requirements of the HIPAA Rules.

8.3 Any ambiguity in this Agreement shall be resolved to permit Covered Entity to comply with the HIPAA Rules.

8.4 In addition to any implied indemnity or express indemnity provision in the Agreement, Business Associate agrees to indemnify, defend and hold harmless the Covered Entity, including any employees, agents, or Subcontractors against any actual and direct losses suffered by the Indemnified Party(ies) and all liability to third parties arising out of or in connection with any breach of this Agreement or from any negligent or wrongful acts or omissions, including failure to perform its obligations under the HIPAA Rules, by the Business Associate or its employees, directors, officers, Subcontractors, agents, or other members of its workforce. Accordingly, upon demand, the Business Associate shall reimburse the Indemnified Party(ies) for any and all actual expenses (including reasonable attorney's fees) which may be imposed upon any Indemnified Party(ies) by reason of any suit, claim, action, proceeding or demand by any third party resulting from the Business Associate's failure to perform, Breach or other action under this Agreement.

SECURITY RULE REQUIREMENTS

9.1 Business Associate agrees, to the extent any Protected Health Information created, received, maintained or transmitted by or in electronic media, also referred to as electronic protected health care information, as defined by 45 CFR § 160.103, that it will only create, maintain or transmit such information with appropriate safeguards in place.

Business Associate shall therefore: implement administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity and availability of the electronic protected health care information; ensure that any agent, including Subcontractors, to whom it provides such information shall agree to also implement reasonable and appropriate safeguards to protect the information; and report to the Covered Entity any Security Incident, as that term is defined by 45 CFR § 164.304, of which it becomes aware.

TERMINATION

10.1 Business Associate authorizes termination of this Agreement by Covered Entity, if Covered Entity determines Business Associate has violated a material term of the Agreement and Business Associate has not cured the breach or ended the violation within the time specified by Covered Entity.

EFFECT OF TERMINATION

11.1 Upon termination of this Agreement for any reason, Business Associate shall return to Covered Entity or, if agreed to by Covered Entity, destroy all Protected Health Information received from Covered Entity, or created, maintained, or received by Business Associate on behalf of Covered Entity, that the Business Associate still maintains in any form. Business Associate shall retain no copies of the Protected Health Information.

Provided however, Business Associate may retain Protected Health Information if necessary for management and administration purposes or to carry out its legal responsibilities after termination of the Agreement.

Upon termination of this Agreement for any reason, Business Associate, with respect to Protected Health Information received from Covered Entity, or created, maintained, or received by Business Associate on behalf of Covered Entity, shall:

retain only that Protected Health Information which is necessary for Business Associate to continue its proper management and administration or to carry out its legal responsibilities;

return to Covered Entity or, if agreed to by Covered Entity, destroy the remaining Protected Health Information that the Business Associate still maintains in any form;

continue to use appropriate safeguards and comply with Subpart C of 45 CFR Part 164 with respect to electronic Protected Health Information to prevent Use or Disclosure of the Protected Health Information, other than as provided for in this Section, for as long as Business Associate retains the Protected Health Information;

not Use or Disclose the Protected Health Information retained by Business Associate other than for the purposes for which such Protected Health Information was retained and subject to the same conditions set out at in this Agreement which applied prior to termination;

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

provided, however, that nothing in this section 11.1 shall apply in the case of PHI remaining in its possession which Business Associate determines it is not feasible to return or destroy. Business Associate shall extend the protection of this Agreement to such PHI and limit further uses and disclosure of such PHI.

The obligations of Business Associate under this Agreement shall survive the termination of this Agreement.

NOTIFICATION OF BREACH

12.1 To the extent Business Associate accesses, maintains, retains, modifies, records, stores, destroys, or otherwise holds, Uses, or Discloses Unsecured Protected Health Information, it shall, following the discovery of a Breach of such information, notify the Covered Entity of such Breach. Such notice shall include the identification of each Individual whose Unsecured Protected Health Information has been, or is reasonably believed by the Business Associate to have been, Used, accessed, acquired, or Disclosed during such Breach. The Business Associate shall provide the Covered Entity with any other available information that the Covered Entity is required to include in notification to the Individual under 45 C.F.R. § 164.404(c) at the time of the required notification to the Covered Entity, or as promptly thereafter as the information is available.

12.2 For purposes of this section, a Breach shall be treated as discovered by the Business Associate as of the first day on which such Breach is known to such Business Associate (including any person, other than the Individual committing the breach, that is an employee, officer, or other agent of such associate) or should reasonably have been known to such Business Associate (or person) to have occurred by the exercise of reasonable diligence.

12.3 Subject to section 12.4, all notifications required under this section shall be made without unreasonable delay and in no case later than 60 calendar days after the discovery of a Breach by the Business Associate involved in the case of a notification required under section 12.2. The Business Associate involved in the case of a notification required under section 12.2, shall have the burden of demonstrating that all notifications were made as required under this part, including evidence demonstrating the necessity of any delay.

12.4 If a law enforcement official determines that a notification or notice required under this section would impede a criminal investigation or cause damage to national security, such notification or notice shall be delayed in the same manner as provided under section 164.528(a)(2) of title 45, Code of Federal Regulations, in the case of a Disclosure covered under such section.

If a law enforcement official states to the Business Associate that any notification or notice would impede a criminal investigation or cause damage to national security, the Business Associate shall:

- (a) If the statement is in writing and specifies the time for which a delay is required, delay such notification or notice for the time period specified by the official; or
- (b) If the statement is made orally, document the statement, including the identity of the official making the statement, and delay the notification or notice temporarily and no longer than 30 days from the date of the oral statement, unless a written statement as described in (a) is submitted during that time.

PROHIBITION ON SALE OF ELECTRONIC HEALTH RECORDS OR PROTECTED HEALTH INFORMATION.

13.1 Except as provided in section 13.2, the Business Associate shall not directly or indirectly receive remuneration in exchange for any Protected Health Information of an Individual unless the Covered Entity has obtained from the Individual, in accordance with section 164.508 of title 45, Code of Federal Regulations, a valid authorization that includes, in accordance with such section, a specification of whether the Protected Health Information can be further exchanged for remuneration by the entity receiving Protected Health Information of that Individual.

13.2 Section 13.1 shall not apply in the following cases:

- (a) The purpose of the exchange is for public health activities (as described in section 164.512(b) of title 45, Code of Federal Regulations).
- (b) The purpose of the exchange is for research (as described in sections 164.501 and 164.512(i) of title 45, Code of Federal Regulations) and the price charged reflects the costs of preparation and transmittal of the data for such purpose.

- (c) The purpose of the exchange is for the treatment of the Individual, subject to any regulation that the Secretary may promulgate to prevent Protected Health Information from inappropriate access, Use, or Disclosure.
- (d) The purpose of the exchange is the health care operation specifically described in subparagraph (iv) of paragraph (6) of the definition of healthcare operations in section 164.501 of title 45, Code of Federal Regulations.
- (e) The purpose of the exchange is for remuneration that is provided by the Covered Entity to the Business Associate for activities involving the exchange of Protected Health Information that the Business Associate undertakes on behalf of and at the specific request of the Covered Entity pursuant to the Agreement.
- (f) The purpose of the exchange is to provide an Individual with a copy of the Individual's Protected Health Information pursuant to section 164.524 of title 45, Code of Federal Regulations.
- (g) The purpose of the exchange is otherwise determined by the Secretary in regulations to be similarly necessary and appropriate as the exceptions provided in subparagraphs (a) through (f).