

REQUEST FOR PROPOSAL

by

The University of Texas Health Science Center at San Antonio

for

**Selection of a Vendor to Provide a
Clinical Trial Management System**

related to

The Office of Clinical Research

RFP No. 745 – 11 P04

Submittal Deadline: Thursday, November 18, 2010, 3:00 p.m., Central Prevailing Time

Pre-Proposal Conference:

The University will hold a pre-proposal conference at **1:00 p.m., Central Prevailing Time** on **Tuesday, November 9, 2010, in Room 104 AAB of the Academics and Administration Building** (ref. APPENDIX THREE Campus Map).

Issued: October 28, 2010

REQUEST FOR PROPOSAL

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SECTION 1

INTRODUCTION

1.1 Description of the University

The **University Of Texas Health Science Center At San Antonio**, one of the fifteen components in The University of Texas System, is a national and international leader in the biosciences. The UTHSCSA was legislatively approved in 1959 as the South Texas Medical School and graduated its first class of medical students in 1970. Since that time, UTHSCSA has evolved into a comprehensive academic health center which includes schools in Medicine, Dentistry, Allied Health, Nursing and Biomedical Sciences. The UTHSCSA also has the oversight responsibility for the Regional Academic Health Center (RAHC), located in the Lower Rio Grande Valley, and the Laredo Campus Extension (LCE), which serves the Mid Rio Grande Valley. The UTHSCSA is proud to share in joint degrees with the University of Texas at San Antonio (UTSA) via the San Antonio Life Sciences Institute (SALSI) and with the University of Texas at Austin.

The UTHSCSA has a student body of 2700 and employs 5300 faculty and staff. The University has acquired an international reputation in Longevity and Aging Studies and oversees a nationally designated cancer center in partnership with The Cancer Therapy and Research Center which complements the very important research being done by the outstanding principal investigators who have been recruited to the Children's Cancer Research Institute. Our clinical programs are consistently cited among the best in *US News and World Report*. Each year, UTHSCSA provides in excess of \$96 million in uncompensated health care to the uninsured and underinsured population of South Texas. Clinical partners include the University Health System, the South Texas Veterans Health Care System, the Christus Santa Rosa Health Care System, and the Valley Baptist Health Care System in Harlingen, Texas.

The UTHSCSA is the only tier one research university in South Texas and we are ranked among the top 10% of all research universities in the nation. The UTHSCSA is responsible for \$180 million of sponsored program funding. Our Health Science Center is the catalyst for the City of San Antonio's \$13 billion health and biosciences industry, which is the leading economic generator for the city. The UTHSCSA also has provided more than 100 active license agreements and 10 new spin-out companies, consistent with the Governor's vision of making Texas a powerhouse in biotechnology. Discoveries coming from UTHSCSA include the Palmaz Stent, one of the top ten patents that have changed the world and which is used to treat over 2 million patients per year world wide, and the Titanium Rib, the first new FDA-approved pediatric device in the past 40 years. The UTHSCSA's annual expenditures of \$500 million contribute in excess of \$2 billion in positive economic impact to Texas yearly. This represents a 20:1 annual return to the citizens of Texas on the \$130 million of state general revenue support currently provided to UTHSCSA through the legislative appropriation process.

1.2 Background and Special Circumstances

The Vice President for Research (VPR) has been charged with enhancing the effectiveness and competitiveness of the research infrastructure at the HSC. The clinical research community acknowledges that a Clinical Trial Management System (CTMS) can improve clinical research management processes, reduce the complexity of processes, improve cost management, and provide superior information flow. In order to

modernize clinical research administration, the VPR Office has determined that a CTMS is necessary to capture data from this research and to manage the activities under protocols and the financials of clinical studies.

The Office of Clinical Research (OCR) develops and maintains quality systems across the HSC research teams. The OCR supports the research community in the conduct of ethical clinical research in compliance with the required federal, state, and local regulations through consultation, education, and training; develops policy and processes; and leads quality improvement efforts in areas of clinical trial management. The Office is charged with ensuring compliance of HSC research teams to good clinical practice as well as clinical trial billing rules and ensuring appropriate education and training for sufficient financial oversight.

Investigators at UTHSCSA initiate over 300 human research studies annually with a cumulative total of over 1,100 ongoing studies.

Principal Investigators (PI) at the HSC are from all five (5) schools and associated departments within the schools, as well as centers and institutes. Furthermore, the HSC research occurs at multiple, affiliated clinics and hospitals-- which means there are multiple billing entities. The VPR's OCR is seeking a unifying electronic CTMS to be established and managed by a new Clinical Trials Office (CTO) and used by research teams across the HSC.

The CTO will be a central office that manages the CTMS and associated business processes throughout the HSC. The objective is to implement a comprehensive solution to decrease the regulatory risk, especially of inappropriate clinical trial (CT) billing, with the added benefit of substantially improving CT revenue. The OCR's assessment of best practices indicates that through the application of appropriate business methods using a CTMS the HSC can increase final budgets per study as well as provide more frequent, timelier, and more effective collection of earned revenue. By shifting CT financial responsibilities to CTO staff with appropriate knowledge and expertise, CT revenues will improve and researchers will be freed from time consuming financial responsibilities, allowing them to focus on enrolling participants and conducting research. The CTO staff will rely on the technical expertise of researchers to provide cost information and conduct the study; and in turn the PIs and their research teams will rely on the CTO to manage the financial responsibilities of the research (i.e. conduct a billing analysis; develop and negotiate effective budgets; track and manage accrued revenue, payments and billing; and reconcile study financial accounts).

The CTO will provide essential services creating a structure of systematic data collection to enable enforcement of regulatory requirements and to facilitate management of the clinical trial enterprise throughout the University. In addition, implementation of a centrally managed CTMS will act as a change agent to develop and enforce standards that will provide capability to capture both quantitative and qualitative measures. The CTMS will provide superior data capture for clinical research and promote regulatory adherence to multiple requirements, e.g. Good Clinical Practices (GCP), Health Insurance Portability and Accountability Act (HIPAA), 21 Code of Federal Regulations (CFR) Part 11. A CTMS does not duplicate the functionality of an electronic medical record (e-MR) or its associated billing system; instead it will track study events and revenues at the study payment level, and will provide the necessary information to billing entities at the patient event level. CTMS implementation will clearly eliminate existing data voids at the study, department, school and institutional levels.

The OCR will establish a cross-functional, cross-organizational CTMS Project Team for design, configuration, implementation, and validation of the CTMS. This process will be lead by OCR which will form a Clinical Trial Unit, CTU, as a precursor to the CTO and will develop associated processes for the CTMS as follow:

- estimation of study costs
- develop and negotiate budgets and contracts that fully fund study cost
- enter study protocol and activities (administrative and clinical) into the CTMS
- track the conduct of the study and the accrued revenues
- track account payables and account receivables
- generate sponsor invoices
- reconcile sponsor payments
- provide reports for all levels of study management

The HSC research staff (PIs and team members) will conduct the studies and use the CTMS to manage the study progress and collect research data.

1.3 Objective of this Request for Proposal

The University of Texas Health Science Center at San Antonio (“**University**”) is soliciting proposals in response to this Request for Proposal for Selection of a Vendor to Provide a Clinical Trial Management System related to the Office of Clinical Research, **RFP No. 745 – 11 P04** (this “**RFP**”), from qualified vendors to provide Clinical Trial Management Systems (the “**Services**”). The Services, which are more specifically described in **Section 5.4** (Scope of Work) of this RFP, include a web-hosted CTMS application, along with vendor implementation support and training services. The contractor shall have expertise with demonstrated success in project management of CTMS implementations that are institution-wide in an Academic Health Center (AHC) of comparable size as the Health Science Center in San Antonio. The contractor will work with the OCR’s Clinical Trial Unit (CTU) and the Health Science Center (HSC)-CTMS Project Team to accomplish the HSC’s CTMS implementation.

1.4 Group Purchase Authority

Texas law authorizes institutions of higher education (defined by Section 61.003, *Education Code*) to use the group purchasing procurement method (ref. Sections 51.9335, 73.115, and 74.008, *Education Code*). Additional Texas institutions of higher education may therefore elect to enter into a contract with the successful Proposer under this RFP.

1.5 The University of Texas System Supply Chain Alliance

The University of Texas Health Science Center at San Antonio is a member of the University of Texas System Supply Chain Alliance (Alliance), a cooperative purchasing initiative comprised of the six health institutions of the University of Texas System (UT System). The Alliance was created to expand the use of joint purchasing and explore new opportunities to leverage the collective size and strength of UT System institutions. The mission of the Alliance is to provide reliable, sustainable solutions for the purchase and delivery of equipment, services, and supplies to support the core missions of education, patient care, and research at UT System institutions.

The Agreement resulting from this solicitation may be extended to additional UT System institutions with the following understandings:

- Any potential extension of contracted pricing and services to any or all UT System institutions may be subject to re-negotiated terms, prices, and services via the Alliance commensurate with participation by Alliance members;
- Unless specifically stated otherwise, any volume of products or services stated in this RFP document reflects only products or services to be purchased by The University of Texas Health Science Center at San Antonio and does not include potential purchases by the Alliance or other UT System institutions; and
- Each UT System campus is a financially separate entity and shall be solely responsible for the financial commitments of that institution.

1.6 Term of the Agreement

This Contract will be in effect for a period of **three (3) years** subject to all the terms and conditions set forth herein. This contract may, upon mutual agreement, be extended for up to **two (2) additional one (1) year periods**. Time is of the essence in the performance of this contract. In the event of any extension of this contract beyond the initial three year period, the UTHSCSA reserves the right to either accept or reject any price adjustments submitted in writing ninety days prior to the end of the current contract period as part of the UTHSCSA consideration for the contract extension.

SECTION 2

NOTICE TO PROPOSER

2.1 Submittal Deadline

University will accept proposals submitted in response to this RFP until **3:00 p.m.**, Central Prevailing Time on **Thursday, November 18, 2010** (the “**Submittal Deadline**”).

2.2 University Contact Person

Proposers will direct all questions or concerns regarding this RFP to the following University contact (the “**University Contact**”):

Christelle Farias
Assistant Director of Purchasing
UTHSCSA
8431 Fredericksburg, Suite #200
San Antonio, TX 78229
fariasc@uthscsa.edu
(210) 562-6202

University specifically instructs all interested parties to restrict all contact and questions regarding this RFP to written communications forwarded to the University Contact. The University Contact must receive all questions or concerns no later than **Thursday, November 11, 2010**. University will have a reasonable amount of time to respond to questions or concerns. It is University’s intent to respond to all appropriate questions and concerns; however, University reserves the right to decline to respond to any question or concern.

2.3 Criteria for Selection

The successful Proposer, if any, selected by University in accordance with the requirements and specifications set forth in this RFP will be the Proposer that submits a proposal in response to this RFP on or before the Submittal Deadline that is the most advantageous to University. The successful Proposer is referred to as the “**Contractor**.”

Proposer is encouraged to propose terms and conditions offering the maximum benefit to University in terms of (1) services to University, (2) total overall cost to University, and (3) project management expertise. Proposers should describe all educational, state and local government discounts, as well as any other applicable discounts that may be available to University in a contract for the Services.

An evaluation team from University will evaluate proposals. The evaluation of proposals and the selection of Contractor will be based on the information provided by Proposer in its proposal. University may give consideration to additional information if University deems such information relevant.

The criteria to be considered by University in evaluating proposals and selecting Contractor, will be those factors listed below:

2.3.1 Threshold Criteria Not Scored

- 2.3.1.1 Ability of University to comply with laws regarding Historically Underutilized Businesses; and
- 2.3.1.2 Ability of University to comply with laws regarding purchases from persons with disabilities.

2.3.2 Scored Criteria

- 2.3.2.1 the cost of goods and services;
- 2.3.2.2 the reputation of the Proposer and of the Proposer's goods or services;
- 2.3.2.3 the quality of the Proposer's goods or services;
- 2.3.2.4 the extent to which the goods or services meet the University's needs;
- 2.3.2.5 the Proposer's past relationship with the University;
- 2.3.2.6 the total long-term cost to the University of acquiring the Proposer's goods or services

2.4 Key Events Schedule

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| Issuance of RFP | Thursday, October 28, 2010 |
| Pre-Proposal Conference (ref. Section 2.6 of this RFP) | Tuesday, November 9, 2010, 1:00 p.m. Central Prevailing Time |
| Deadline for Questions/Concerns (ref. Section 2.2 of this RFP) | Thursday, November 11, 2010 |
| Submittal Deadline (ref. Section 2.1 of this RFP) | 3:00 p.m. Central Prevailing Time on Thursday, November 18, 2010 |

2.5 Historically Underutilized Businesses

- 2.5.1 All agencies of the State of Texas are required to make a good faith effort to assist historically underutilized businesses (each a "HUB") in receiving contract awards. The goal of the HUB program is to promote full and equal business opportunity for all businesses in contracting with state agencies. Pursuant to the HUB program, if under the terms of any agreement or contractual arrangement resulting from this RFP, Contractor subcontracts any of the Services, then Contractor must make a good faith effort to utilize HUBs certified by the Texas Procurement and Support Services Division of the Texas Comptroller of Public Accounts or any successor agency. Proposals that fail to comply with the requirements contained in this Section 2.5 will constitute a material failure to comply with advertised specifications and will be rejected by the University as non-responsive. Additionally, compliance with good faith effort guidelines is a condition precedent to awarding any agreement or contractual arrangement resulting from this RFP. Proposer acknowledges that, if selected by University, its obligation to make a good faith effort to utilize HUBs when subcontracting any of the Services will continue throughout the term of all agreements and contractual arrangements resulting from this RFP. Furthermore, any subcontracting of the Services by the Proposer is subject to review by the University to ensure compliance with the HUB program.

- 2.5.2 The University has reviewed this RFP in accordance with Title 34, Texas Administrative Code, Section 20.13 (a), and has determined that subcontracting opportunities are probable under this RFP.
- 2.5.3 A HUB Subcontracting Plan (“**HSP**”) is required as part of Proposer’s proposal. The HSP will be developed and administered in accordance with University’s Policy on Utilization of Historically Underutilized Businesses attached as **APPENDIX TWO** and incorporated for all purposes.

*Each Proposer must complete and return the HSP in accordance with the terms and conditions of this RFP, including **APPENDIX TWO**. Proposers that fail to do so will be considered non-responsive to this RFP in accordance with Section 2161.252, Government Code.*

Contractor will not be permitted to change its HSP unless: (1) Contractor completes a newly modified version of the HSP in accordance with the terms of **APPENDIX TWO** that sets forth all changes requested by Contractor, (2) Contractor provides the University with such a modified version of the HSP, (3) the University approves the modified HSP in writing, and (4) all agreements or contractual arrangements resulting from this RFP are amended in writing by the University and Contractor to conform to the modified HSP.

- 2.5.4 Proposer must submit **one (1) original** of the HSP to the University at the same time it submits its proposal to the University (ref. **Section 3.2** of this RFP.) The **one (1) original** of the HSP must be submitted under separate cover and in a separate envelope (the “**HSP Envelope**”). Proposer must ensure that the top outside surface of its HSP Envelope clearly shows and makes visible:

- 2.5.4.1 the RFP No. (ref. **Section 1.3** of this RFP) and the Submittal Deadline (ref. **Section 2.1** of this RFP), both located in the lower left hand corner of the top surface of the envelope,
- 2.5.4.2 the name and the return address of the Proposer, and
- 2.5.4.3 the phrase “HUB Subcontracting Plan”.

Any proposal submitted in response to this RFP that is not accompanied by a separate HSP Envelope meeting the above requirements will be rejected by the University and returned to the Proposer unopened as that proposal will be considered non-responsive due to material failure to comply with advertised specifications. Furthermore, the University will open a Proposer’s HSP Envelope prior to opening the proposal submitted by the Proposer, in order to ensure that the Proposer has submitted the number of completed and signed originals of the Proposer’s HSP that are required by this RFP. A Proposer’s failure to submit the number of completed and signed originals of the HSP that are required by this RFP will result in the University’s rejection of the proposal submitted by that Proposer as non-responsive due to material failure to comply with advertised specifications; such a proposal will be returned to the Proposer unopened. (Ref. **Section 1.5** of **APPENDIX ONE** to this RFP.) **Note:** The requirement that Proposer provide **one (1) original** of the HSP under this **Section 2.5.4** is separate from and does not affect Proposer’s obligation to provide the University with the number of copies of its proposal as specified in **Section 3.1** of this RFP.

2.6 Pre-Proposal Conference

University will hold a pre-proposal conference at **1:00 p.m.**, Central Prevailing Time on **Tuesday, November 9, 2010, in Room 104 AAB of the Academics and Administration Building** (ref. **APPENDIX THREE Campus Map**). The pre-proposal conference will allow all Proposers an opportunity to ask University's representatives relevant questions and clarify provisions of this RFP.

SECTION 3

SUBMISSION OF PROPOSAL

3.1 Number of Copies

Proposer must submit a total of **eight (8)** complete and identical copies of its *entire* proposal. An *original* signature by an authorized officer of Proposer must appear on the Execution of Offer (ref. **Section 2** of **APPENDIX ONE**) of at least one (1) copy of the submitted proposal. The copy of the Proposer's proposal bearing an original signature should contain the mark "original" on the front cover of the proposal.

3.2 Submission

Proposals must be received by University on or before the Submittal Deadline (ref. **Section 2.1** of this RFP) and should be delivered to:

Christelle Farias
Assistant Director of Purchasing
UTHSCSA
Purchasing Department
8431 Fredericksburg Rd., Suite #200
San Antonio, TX 78229
(210) 562-6202

3.3 Proposal Validity Period

Each proposal must state that it will remain valid for University's acceptance for a minimum of **one hundred and eighty (180) days** after the Submittal Deadline, to allow time for evaluation, selection, and any unforeseen delays.

3.4 Terms and Conditions

3.4.1 Proposer must comply with the requirements and specifications contained in this RFP, the Terms and Conditions (ref. **Section 4** of this RFP), the Notice to Proposer (ref. **Section 2** of this RFP), Proposal Requirements (ref. **APPENDIX ONE**) and the Specifications and Additional Questions (ref. **Section 5** of this RFP). If there is a conflict among the provisions in this RFP, the provision requiring Proposer to supply the better quality or greater quantity of services will prevail, or if such conflict does not involve quality or quantity, then interpretation will be in the following order of precedence:

- 3.4.1.1. Specifications and Additional Questions (ref. **Section 5** of this RFP);
- 3.4.1.2. Terms and Conditions (ref. **Section 4** of this RFP);
- 3.4.1.3. Proposal Requirements (ref. **APPENDIX ONE**);
- 3.4.1.4. Notice to Proposers (ref. **Section 2** of this RFP).

3.5 Submittal Checklist

Proposer is instructed to complete, sign, and return the following documents as a part of its proposal. If Proposer fails to return each of the following items with its proposal, then University may reject the proposal:

- 3.5.1 Signed and Completed Execution of Offer (ref. **Section 2 of APPENDIX ONE**)
- 3.5.2 Signed and Completed Pricing and Delivery Schedule (ref. **Section 6** of this RFP)
- 3.5.3 Responses to Proposer's General Questionnaire (ref. **Section 3 of APPENDIX ONE**)
- 3.5.4 Signed and Completed Addenda Checklist (ref. **Section 4 of APPENDIX ONE**)
- 3.5.5 Responses to questions and requests for information in the Specifications and Additional Questions Section (ref. **Section 5** of this RFP)
- 3.5.6 Signed and completed originals of the HUB Subcontracting Plan (ref. **Section 2.5** of this RFP and **APPENDIX TWO**).

SECTION 4

GENERAL TERMS AND CONDITIONS

4.1 General

The terms and conditions contained in this **Section 4** or, in the sole discretion of University, terms and conditions substantially similar to these terms and conditions, and the Business Associate Agreement (**APPENDIX SIX**), will be included in any contract or agreement that results from this RFP (ref. **Section 1.4** of **APPENDIX ONE**).

As indicated in **Section 2.3** of this RFP, the successful Proposer is referred to as the **“Contractor.”**

If Proposer takes exception to any terms or conditions set forth in this **Section 4**, or the Business Associate Agreement (**APPENDIX SIX**), Proposer will submit a list of the exceptions as part of its proposal, in accordance with **Section 5.3.3** of this RFP. Proposer's exceptions will be reviewed by UTHSCSA and may result in disqualification of Proposer's proposal as non-responsive to this RFP. If Proposer's exceptions do not result in disqualification of Proposer's proposal, then UTHSCSA may consider Proposer's exceptions when UTHSCSA evaluates Proposer's proposal.

4.2 Payment

University agrees to pay fees due under this Agreement in accordance with the Texas Prompt Payment Act (“**Act**”), Chapter 2251, *Government Code*. Pursuant to the Act, payment shall be deemed late on the 31st day after the later of: 1) the date the performance of the Services under this Agreement are completed, or 2) the date University receives an invoice for the Services. University will be responsible for interest on overdue payments equal to the sum of: 1) one percent, plus 2) the prime rate as published in the Wall Street Journal on the first day of July of the preceding fiscal year (University's fiscal year begins September 1) that does not fall on a Saturday or Sunday. University will have the right to verify the details set forth in Contractor's invoices and supporting documentation, either before or after payment, by (a) inspecting the books and records of Contractor at mutually convenient times; (b) examining any reports with respect to the Project; and (c) other reasonable action. The cumulative amount of all payments will not exceed the amount of this Agreement.

4.3 Tax Exemption

University, an agency of the State of Texas, is exempt from Texas Sales & Use Tax on the Services in accordance with Section 151.309, *Tax Code*, and Title 34 *Texas Administrative Code* (“**TAC**”) Section 3.322.

4.5 Contractor's Obligations.

4.5.1 Contractor will perform the Services in compliance with all applicable federal, state and local, laws, regulations, and ordinances. Contractor represents and warrants that neither Contractor nor any firm, corporation or institution represented by Contractor, or anyone acting for the firm, corporation or institution, (1) has violated the antitrust laws of the State of Texas, Chapter 15, *Business and Commerce Code*, or federal antitrust laws, or (2) has communicated directly or

indirectly the content of Contractor's response to University's procurement solicitation to any competitor or any other person engaged in a similar line of business during the procurement process for this Agreement.

- 4.5.2 Contractor represents, warrants and agrees that (a) it will use commercially reasonable efforts to perform the Services in a good and workmanlike manner and in accordance with commercially reasonable standards of Contractor's profession or business, and (b) all of the Services to be performed will be of the quality that prevails among similar businesses engaged in providing similar services in major United States urban areas under the same or similar circumstances
- 4.5.3 Contractor will call to University's attention in writing all information in any materials supplied to Contractor (by University or any other party) that Contractor regards as unsuitable, improper or inaccurate in connection with the purposes for which the material is furnished.
- 4.5.4 Contractor warrants and agrees that the Services will be accurate and free from any material defects. Contractor's duties and obligations under this Agreement will at no time be in any way diminished by reason of any approval by University nor will Contractor be released from any liability by reason of any approval by University, it being agreed that University at all times is relying upon Contractor's skill and knowledge in performing the Services.
- 4.5.5 Contractor will, at its own cost, correct all material defects in the Services as soon as practical after Contractor becomes aware of the defects. If Contractor fails to correct material defects in the Services within a reasonable time, then University may correct the defective Services at Contractor's expense. This remedy is in addition to, and not in substitution for, any other remedy for defective Services that University may have at law or in equity.
- 4.5.6 Contractor will maintain a staff of properly trained and experienced personnel to ensure satisfactory performance under this Agreement. Contractor will cause all persons connected with Contractor directly in charge of the Services to be duly registered and/or licensed under all applicable federal, state and local, laws, regulations, and ordinances. Contractor will assign to the Project a designated representative who will be responsible for the administration and coordination of the Services.
- 4.5.7 Contractor represents that if (i) it is a corporation, then it is a corporation duly organized, validly existing and in good standing under the laws of the State of Texas, or a foreign corporation or limited liability company duly authorized and in good standing to conduct business in the State of Texas, that it has all necessary corporate power and has received all necessary corporate approvals to execute and deliver this Agreement, and the individual executing this Agreement on behalf of Contractor has been duly authorized to act for and bind Contractor; or (ii) if it is a partnership, limited partnership, limited liability partnership, or limited liability company then it has all necessary power and has secured all necessary approvals to execute and deliver this Agreement and perform all its obligations hereunder, and the individual executing this Agreement on behalf of Contractor has been duly authorized to act for and bind Contractor.
- 4.5.8 Contractor represents and warrants that neither the execution and delivery of this Agreement by Contractor nor the performance of its duties and obligations under this Agreement will (a) result in the violation of any provision [i] if a corporation, of

- Contractor's articles of incorporation or by-laws, [ii] if a limited liability company, of its articles of organization or regulations, or [iii] if a partnership, of any partnership agreement by which Contractor is bound; (b) result in the violation of any provision of any agreement by which Contractor is bound; or (c) to the best of Contractor's knowledge and belief, conflict with any order or decree of any court or other body or authority having jurisdiction.
- 4.5.9 Contractor represents and warrants that all of Contractor's Personnel contributing to the Work Material (ref. **Section 4.26**) under this Agreement will be required to (i) acknowledge in writing the ownership of Contractor (for the benefit of University) of the Work Material and each element thereof produced by the Personnel while performing services pursuant to this Agreement and (ii) make all assignments necessary to effectuate such ownership. "**Personnel**" means any and all persons associated with Contractor who provide any work or work product pursuant to this Agreement, including officers, managers, supervisors, full-time employees, part-time employees, and independent contractors.
- 4.5.10 Contractor represents and warrants that: (i) the Services will be performed solely by Contractor, its full-time or part-time employees during the course of their employment, or independent contractors who have assigned in writing all right, title and interest in their work to Contractor for the benefit of University; (ii) University will receive free, good and clear title to all Work Material developed under this Agreement; (iii) the Work Material and the intellectual property rights protecting the Work Material are free and clear of all encumbrances, including security interests, licenses, liens, charges or other restrictions; (iv) the Work Material will not infringe upon or violate any patent, copyright, trade secret, trademark, service mark or other property right of any former employer, independent contractor, client or other third party; and (v) the use, reproduction, distribution, or modification of the Work Material will not violate the rights of any third parties in the Work Material, including trade secret, publicity, privacy, copyright, trademark, service mark and patent rights.
- 4.5.11 If this Agreement requires Contractor's presence on University's premises or in University's facilities, Contractor agrees to cause its representatives, agents, employees and subcontractors to become aware of, fully informed about, and in full compliance with all applicable University rules and policies, including those relative to personal health, security, environmental quality, safety, fire prevention, noise, smoking, and access restrictions.

4.6 Family Code Child Support Certification

Pursuant to Section 231.006, *Family Code*, Contractor certifies that it is not ineligible to receive the award of or payments under this Agreement and acknowledges that this Agreement may be terminated and payment may be withheld if this certification is inaccurate.

4.7 Eligibility Certifications

Pursuant to Sections 2155.004 and 2155.006, *Government Code*, Contractor certifies that Contractor is not ineligible to receive the award of or payments under this Agreement and acknowledges that this Agreement may be terminated and payment withheld if this certification is inaccurate.

4.8 Tax Certification

If Contractor is a taxable entity as defined by Chapter 171, *Tax Code* ("Chapter 171"), then Contractor certifies that it is not currently delinquent in the payment of any taxes due under Chapter 171, or that Contractor is exempt from the payment of those taxes, or that Contractor is an out-of-state taxable entity that is not subject to those taxes, whichever is applicable.

4.9 Payment of Debt or Delinquency to the State

Pursuant to Sections 2107.008 and 2252.903, *Government Code*, Contractor agrees that any payments owing to Contractor under this Agreement may be applied directly toward any debt or delinquency that Contractor owes the State of Texas or any agency of the State of Texas regardless of when it arises, until such debt or delinquency is paid in full.

4.10 Products and Materials Produced in Texas

If Contractor will provide services under this Agreement, Contractor covenants and agrees that in accordance with Section 2155.4441, *Government Code*, in performing its duties and obligations under this Agreement, Contractor shall purchase products and materials produced in Texas when such products and materials are available at a price and delivery time comparable to products and materials produced outside of Texas.

4.11 Loss of Funding

Performance by University under this Agreement may be dependent upon the appropriation and allotment of funds by the Texas State Legislature (the "**Legislature**") and/or allocation of funds by the Board of Regents of The University of Texas System (the "**Board**"). If the Legislature fails to appropriate or allot the necessary funds, or the Board fails to allocate the necessary funds, then University shall issue written notice to Contractor and University may terminate this Agreement without further duty or obligation hereunder. Contractor acknowledges that appropriation, allotment, and allocation of funds are beyond the control of University.

4.12 Notices

Except as otherwise provided in this Section, all notices, consents, approvals, demands, requests or other communications provided for or permitted to be given under any of the provisions of this Agreement will be in writing and will be sent via registered or certified mail, overnight courier, confirmed facsimile transmission (to the extent a facsimile number is set forth below), or email (to the extent an email address is set forth below), and notice will be deemed given (i) if mailed, when deposited, postage prepaid, in the United States mail, (ii) if sent by overnight courier, one business day after delivery to the courier, (iii) if sent by facsimile (to the extent a facsimile number is set forth below), when transmitted, and (iv) if sent by email (to the extent an email address is set forth below), when received:

If to University: The University of Texas Health Science Center at San Antonio
Vikki Ross, Director of Purchasing
7703 Floyd Curl Drive; Mail Code 7962
San Antonio, TX 78229-3900
Email: purchadmin@uthscsa.edu
Tel: (210) 562-6200; Fax: 210-562-6290

with copy to: The University of Texas Health Science Center at San Antonio
Attn: Mike Charlton
Assistant Vice President for Risk Management and Safety
Environmental Health & Safety
7703 Floyd Curl Drive
San Antonio, TX 78229-3900
Email: charlton@uthscsa.edu
Tel.: (210) 567-2955; Fax: (210) 567-2965

If to Contractor: _____

Attention: _____

or other person or address as may be given in writing by either party to the other in accordance with this Section.

Notwithstanding any other requirements for notices given by a party under this Agreement, if Contractor intends to deliver written notice to University pursuant to Section 2251.054, *Government Code*, then Contractor will send that notice to University as follows:

The University of Texas Health Science Center at San Antonio
Vikki Ross, Director of Purchasing
7703 Floyd Curl Drive; Mail Code 7962
San Antonio, TX 78229-3900
Email: purchadmin@uthscsa.edu
Tel: (210) 562-6200; Fax: 210-562-6290

with copy to: The University of Texas Health Science Center at San Antonio
Attn: Mike Charlton
Assistant Vice President for Risk Management and Safety
Environmental Health & Safety
7703 Floyd Curl Drive
San Antonio, TX 78229-3900
Email: charlton@uthscsa.edu
Tel.: (210) 567-2955; Fax: (210) 567-2965

or other person or address as may be given in writing by University to Contractor in accordance with this Section.

4.13 State Auditor's Office

Contractor understands that acceptance of funds under this Agreement constitutes acceptance of the authority of the Texas State Auditor's Office, or any successor agency (collectively, "**Auditor**"), to conduct an audit or investigation in connection with those funds pursuant to Sections 51.9335(c), 73.115(c) and 74.008(c), *Education Code*. Contractor agrees to cooperate with the Auditor in the conduct of the audit or investigation including providing all records requested. Contractor will include this provision in all contracts with permitted subcontractors.

4.14 Venue; Governing Law

Bexar County, Texas, shall be the proper place of venue for suit on or in respect of this Agreement. This Agreement and all of the rights and obligations of the parties hereto and all of the terms and conditions hereof shall be construed, interpreted and applied in accordance with and governed by and enforced under the laws of the State of Texas.

4.15 Breach of Contract Claims

4.15.1 To the extent that Chapter 2260, *Government Code*, as it may be amended from time to time ("**Chapter 2260**"), is applicable to this Agreement and is not preempted by other applicable law, the dispute resolution process provided for in Chapter 2260 will be used, as further described herein, by University and Contractor to attempt to resolve any claim for breach of contract made by Contractor:

4.15.1.1 Contractor's claims for breach of this Agreement that the parties cannot resolve pursuant to other provisions of this Agreement or in the ordinary course of business will be submitted to the negotiation process provided in subchapter B of Chapter 2260. To initiate the process, Contractor will submit written notice, as required by subchapter B of Chapter 2260, to University in accordance with the notice provisions in this Agreement. Contractor's notice will specifically state that the provisions of subchapter B of Chapter 2260 are being invoked, the date and nature of the event giving rise to the claim, the specific contract provision that University allegedly breached, the amount of damages Contractor seeks, and the method used to calculate the damages. Compliance by Contractor with subchapter B of Chapter 2260 is a required prerequisite to Contractor's filing of a contested case proceeding under subchapter C of Chapter 2260. The Chief Business Officer of University, or the other officer of University as may be designated from time to time by University by written notice thereof to Contractor in accordance with the notice provisions in this Agreement, will examine Contractor's claim and any counterclaim and negotiate with Contractor in an effort to resolve the claims.

4.15.1.2 If the parties are unable to resolve their disputes under Section 4.16.1.1, the contested case process provided in subchapter C of Chapter 2260 is Contractor's sole and exclusive process for seeking a remedy for any and all of Contractor's claims for breach of this Agreement by University.

4.15.1.3 Compliance with the contested case process provided in subchapter C of Chapter 2260 is a required prerequisite to seeking consent to sue from the Legislature under Chapter 107, *Civil Practices and Remedies Code*. The parties hereto specifically agree that (i) neither the execution of this Agreement by University nor any other conduct, action or inaction of any representative of University relating to this Agreement constitutes or is intended to constitute a waiver of University's or the state's sovereign immunity to suit and (ii) University has not waived its right to seek redress in the courts.

4.15.2 The submission, processing and resolution of Contractor's claim is governed by the published rules adopted by the Texas Attorney General pursuant to Chapter 2260, as currently effective, thereafter enacted or subsequently amended.

4.15.3 University and Contractor agree that any periods set forth in this Agreement for notice and cure of defaults are not waived.

4.16 Compliance with Law

Contractor will perform the Services in compliance with all applicable federal, state and local, laws, regulations, and ordinances. Contractor represents and warrants that neither Contractor nor any firm, corporation or institution represented by Contractor, or anyone acting for the firm, corporation or institution, (1) has violated the antitrust laws of the State of Texas, Chapter 15, *Business and Commerce Code*, or federal antitrust laws, or (2) has communicated directly or indirectly the content of Contractor's response to University's procurement solicitation to any competitor or any other person engaged in a similar line of business during the procurement process for this Agreement.

4.17 Records

Records of Contractor's costs, any reimbursable expenses pertaining to the Services and payments will be available to University or its authorized representative during business hours and will be retained for four (4) years after final payment or abandonment of the Services, unless University otherwise instructs Contractor in writing.

4.18 Insurance

4.18.1 Contractor, consistent with its status as an independent contractor will carry and will cause its subcontractors to carry, at least the following insurance in the form, with companies having an A.M. Best Rating of A-IV or better, and in amounts (unless otherwise specified), as University may require:

| | |
|----------|---|
| 4.18.1.1 | Workers' Compensation Insurance with statutory limits, and Employer's Liability Insurance with limits of not less than \$1,000,000: |
| | Employers Liability - Each Accident \$1,000,000 |
| | Employers Liability - Each Employee \$1,000,000 |
| | Employers Liability - Policy Limit \$1,000,000 |

Policies must include (a) Other States Endorsement to include TEXAS if business is domiciled outside the State of Texas, and (b) a waiver of all rights of subrogation and other rights in favor of University;

| | |
|----------|--|
| 4.18.1.2 | Commercial General Liability Insurance with limits of not less than: |
| | Each Occurrence Limit \$1,000,000 |
| | Damage to Rented Premises \$ 100,000 |
| | Medical Expenses (any one person) \$ 10,000 |
| | Personal & Advertising Injury \$1,000,000 |
| | General Aggregate \$2,000,000 |
| | Products - Completed Operations Aggregate \$2,000,000 |

4.18.1.3 Commercial Automobile Liability Insurance covering all owned, non-owned or hired automobiles, with coverage for at least \$1,000,000 Combined Single Limit Bodily Injury and Property Damage

4.18.2 Contractor will deliver to University:

- 4.18.2.1 Evidence satisfactory to University in its sole discretion, evidencing the existence of all insurance promptly after the execution and delivery of this Agreement and prior to the performance or continued performance of any services to be performed by Contractor under this Agreement.
 - 4.18.2.2 Additional evidence, satisfactory to University in its sole discretion, of the continued existence of all insurance not less than thirty (30) days prior to the expiration of any insurance. Insurance policies, with the exception of Workers' Compensation, will name and the evidence will reflect University as an Additional Insured and will provide that the policies will not be canceled until after thirty (30) days' unconditional written notice to University.
- 4.18.3 The insurance policies required in this Agreement will be kept in force for the periods specified below:
- 4.18.3.1 Commercial General Liability Insurance, Commercial Automobile Liability Insurance, will be kept in force until receipt of Final Payment by University to Contractor; and
 - 4.18.3.2 Workers' Compensation Insurance and Employer's Liability Insurance will be kept in force until the Services has been fully performed and accepted by University in writing.

4.19 Indemnification

- 4.19.1 TO THE FULLEST EXTENT PERMITTED BY LAW, CONTRACTOR WILL AND DOES HEREBY AGREE TO INDEMNIFY, PROTECT, DEFEND WITH COUNSEL APPROVED BY UNIVERSITY, AND HOLD HARMLESS UNIVERSITY AND THE UNIVERSITY OF TEXAS SYSTEM, AND THEIR RESPECTIVE AFFILIATED ENTERPRISES, REGENTS, OFFICERS, DIRECTORS, ATTORNEYS, EMPLOYEES, REPRESENTATIVES AND AGENTS (COLLECTIVELY "**INDEMNITEES**") FROM AND AGAINST ALL DAMAGES, LOSSES, LIENS, CAUSES OF ACTION, SUITS, JUDGMENTS, EXPENSES, AND OTHER CLAIMS OF ANY NATURE, KIND, OR DESCRIPTION, INCLUDING REASONABLE ATTORNEYS' FEES INCURRED IN INVESTIGATING, DEFENDING OR SETTLING ANY OF THE FOREGOING (COLLECTIVELY "**CLAIMS**") BY ANY PERSON OR ENTITY, ARISING OUT OF, CAUSED BY, OR RESULTING FROM CONTRACTOR'S PERFORMANCE UNDER OR BREACH OF THIS AGREEMENT AND THAT ARE CAUSED IN WHOLE OR IN PART BY ANY NEGLIGENT ACT, NEGLIGENT OMISSION OR WILLFUL MISCONDUCT OF CONTRACTOR, ANYONE DIRECTLY EMPLOYED BY CONTRACTOR OR ANYONE FOR WHOSE ACTS CONTRACTOR MAY BE LIABLE. THE PROVISIONS OF THIS SECTION WILL NOT BE CONSTRUED TO ELIMINATE OR REDUCE ANY OTHER INDEMNIFICATION OR RIGHT WHICH ANY INDEMNITEE HAS BY LAW OR EQUITY. ALL PARTIES WILL BE ENTITLED TO BE REPRESENTED BY COUNSEL AT THEIR OWN EXPENSE.

- 4.19.2 IN ADDITION, CONTRACTOR WILL AND DOES HEREBY AGREE TO INDEMNIFY, PROTECT, DEFEND WITH COUNSEL APPROVED BY UNIVERSITY, AND HOLD HARMLESS INDEMNITEES FROM AND AGAINST ALL CLAIMS ARISING FROM INFRINGEMENT OR ALLEGED INFRINGEMENT OF ANY PATENT, COPYRIGHT, TRADEMARK OR OTHER

PROPRIETARY INTEREST ARISING BY OR OUT OF THE PERFORMANCE OF SERVICES OR THE PROVISION OF GOODS BY CONTRACTOR, OR THE USE BY INDEMNITEES, AT THE DIRECTION OF CONTRACTOR, OF ANY ARTICLE OR MATERIAL; PROVIDED, THAT, UPON BECOMING AWARE OF A SUIT OR THREAT OF SUIT FOR INFRINGEMENT, UNIVERSITY WILL PROMPTLY NOTIFY CONTRACTOR AND CONTRACTOR WILL BE GIVEN THE OPPORTUNITY TO NEGOTIATE A SETTLEMENT. IN THE EVENT OF LITIGATION, UNIVERSITY AGREES TO REASONABLY COOPERATE WITH CONTRACTOR. ALL PARTIES WILL BE ENTITLED TO BE REPRESENTED BY COUNSEL AT THEIR OWN EXPENSE.

4.20 Ethics Matters; No Financial Interest

Contractor and its employees, agents, representatives and subcontractors have read and understand University's Conflicts of Interest Policy available at <http://www.uthscsa.edu/compliance>, and <http://www.uthscsa.edu/hop2000/10.1.12.pdf>. University's Standards of Conduct Guide available at <http://www.uthscsa.edu/compliance>, and <http://www.uthscsa.edu/hop2000/10.1.2.pdf>, and applicable state ethics laws and rules available at www.utsystem.edu/ogc/ethics. Neither Contractor nor its employees, agents, representatives or subcontractors will assist or cause University employees to violate University's Conflicts of Interest Policy, provisions described by University's Standards of Conduct Guide, or applicable state ethics laws or rules. Contractor represents and warrants that no member of the Board has a direct or indirect financial interest in the transaction that is the subject of this Agreement.

4.21 Undocumented Workers. The *Immigration and Nationality Act* (8 *United States Code* 1324a) ("**Immigration Act**") makes it unlawful for an employer to hire or continue employment of undocumented workers. The United States Immigration and Customs Enforcement Service has established the Form I-9 Employment Eligibility Verification Form ("**I-9 Form**") as the document to be used for employment eligibility verification (8 *Code of Federal Regulations* 274a). Among other things, Contractor is required to: (1) have all employees complete and sign the I-9 Form certifying that they are eligible for employment; (2) examine verification documents required by the I-9 Form to be presented by the employee and ensure the documents appear to be genuine and related to the individual; (3) record information about the documents on the I-9 Form, and complete the certification portion of the I-9 Form; and (4) retain the I-9 Form as required by law. It is illegal to discriminate against any individual (other than a citizen of another country who is not authorized to work in the United States) in hiring, discharging, or recruiting because of that individual's national origin or citizenship status. If Contractor employs unauthorized workers during performance of this Agreement in violation of the Immigration Act then, in addition to other remedies or penalties prescribed by law, University may terminate this Agreement in accordance with **Section 4.29**. Contractor represents and warrants that it is in compliance with and agrees that it will remain in compliance with the provisions of the Immigration Act.

4.22 Force Majeure. Neither party hereto will be liable or responsible to the other for any loss or damage or for any delays or failure to perform due to causes beyond its reasonable control including acts of God, strikes, epidemics, war, riots, flood, fire, sabotage, or any other circumstances of like character ("**force majeure occurrence** Provided, however, in the event of a force majeure occurrence, Contractor agrees to use its best efforts to mitigate the impact of the occurrence so that University may continue to provide healthcare services during the occurrence.

4.23 Entire Agreement; Modifications. This Agreement supersedes all prior agreements, written or oral, between Contractor and University and will constitute the entire agreement and understanding between the parties with respect to the subject matter of this Agreement. This Agreement and each of its provisions will be binding upon the parties and may not be waived, modified, amended or altered except by a writing signed by both University and Contractor.

4.24 Captions

The captions of sections and subsections in this Agreement are for convenience only and will not be considered or referred to in resolving questions of interpretation or construction.

4.25 Waivers

No delay or omission in exercising any right accruing upon a default in performance of this Agreement will impair any right or be construed to be a waiver of any right. A waiver of any default under this Agreement will not be construed to be a waiver of any subsequent default under this Agreement.

4.26 Ownership and Use of Work Material

4.26.1 All drawings, specifications, plans, computations, sketches, data, photographs, tapes, renderings, models, publications, statements, accounts, reports, studies, and other materials prepared by Contractor or any subcontractors in connection with the Services (collectively, "**Work Material**"), whether or not accepted or rejected by University, are the sole property of University and for its exclusive use and re-use at any time without further compensation and without any restrictions.

4.26.2 Contractor grants and assigns to University all rights and claims of whatever nature and whether now or hereafter arising in and to the Work Material and will cooperate fully with University in any steps University may take to obtain or enforce patent, copyright, trademark or like protections with respect to the Work Material.

4.26.3 Contractor will deliver all Work Material to University upon expiration or termination of this Agreement. University will have the right to use the Work Material for the completion of the Services or otherwise. University may, at all times, retain the originals of the Work Material. The Work Material will not to be used by any person other than University on other projects unless expressly authorized by University in writing.

4.26.4 The Work Material will not be used or published by Contractor or any other party unless expressly authorized by University in writing. Contractor will treat all Work Material as confidential.

4.26.5 All title and interest in the Work Material will vest in University and will be deemed to be a work made for hire and made in the course of the Services rendered under this Agreement. To the extent that title to any Work Material may not, by operation of law, vest in University or Work Material may not be considered works made for hire, Contractor hereby irrevocably assigns, conveys and transfers to University and its successors, licensees and assigns, all rights, title and interest worldwide in and to the Work Material and all proprietary rights therein, including all copyrights, trademarks, service marks, patents, trade secrets, moral rights, all contract and licensing rights and all claims and causes of action with respect to any of the foregoing, whether now known or hereafter to become known. In the event

Contractor has any rights in the Work Material which cannot be assigned, Contractor agrees to waive enforcement worldwide of the rights against University, its successors, licensees, assigns, distributors and customers or, if necessary, to exclusively license the rights, worldwide to University with the right to sublicense. These rights are assignable by University.

4.27 Confidentiality and Safeguarding of University Records; Press Releases; Public Information

Under this Agreement, Contractor may (1) create, (2) receive from or on behalf of University, or (3) have access to, records or record systems (collectively, "**University Records**"). Among other things, University Records may contain social security numbers, credit card numbers, or data protected or made confidential or sensitive by applicable federal, state and local, laws, regulations, and ordinances, including the Gramm-Leach-Bliley Act (Public Law No: 106-102) and the Family Educational Rights and Privacy Act, 20 U.S.C. §1232g ("**FERPA**"). If University Records are subject to FERPA, (1) University designates Contractor as a University official with a legitimate educational interest in University Records, and (2) Contractor acknowledges that its improper disclosure or redisclosure of personally identifiable information from University Records will result in Contractor's exclusion from eligibility to contract with University for at least five (5) years. Contractor represents, warrants, and agrees that it will: (1) hold University Records in strict confidence and will not use or disclose University Records except as (a) permitted or required by this Agreement, (b) required by law, or (c) otherwise authorized by University in writing; (2) safeguard University Records according to reasonable administrative, physical and technical standards (such as standards established by (i) the National Institute of Standards and Technology and (ii) the Center for Internet Security, as well as the Payment Card Industry Data Security Standards) that are no less rigorous than the standards by which Contractor protects its own confidential information; (3) continually monitor its operations and take any action necessary to assure that University Records are safeguarded and the confidentiality of University Records is maintained in accordance with all applicable federal, state and local, laws, regulations, and ordinances, including FERPA and the Gramm-Leach Bliley Act, and the terms of this Agreement; and (4) comply with the University's rules, policies, and procedures regarding access to and use of University's computer systems. At the request of University, Contractor agrees to provide University with a written summary of the procedures Contractor uses to safeguard and maintain the confidentiality of University Records.

4.27.1 Notice of Impermissible Use. If an impermissible use or disclosure of any University Records occurs, Contractor will provide written notice to University within one (1) business day after Contractor's discovery of that use or disclosure. Contractor will promptly provide University with all information requested by University regarding the impermissible use or disclosure.

4.27.2 Return of University Records. Contractor agrees that within thirty (30) days after the expiration or termination of this Agreement, for any reason, all University Records created or received from or on behalf of University will be (1) returned to University, with no copies retained by Contractor; or (2) if return is not feasible, destroyed. Twenty (20) days before destruction of any University Records, Contractor will provide University with written notice of Contractor's intent to destroy University Records. Within five (5) days after destruction, Contractor will confirm to University in writing the destruction of University Records.

4.27.3 **Disclosure.** If Contractor discloses any University Records to a subcontractor or agent, Contractor will require the subcontractor or agent to comply with the same restrictions and obligations as are imposed on Contractor by this Section.

4.27.4 **Press Releases.** Except when defined as part of the Services, Contractor will not make any press releases, public statements, or advertisement referring to the Project or the engagement of Contractor as an independent contractor of University in connection with the Project, or release any information relative to the Project for publication, advertisement or any other purpose without the prior written approval of University.

4.27.5 **Public Information.** University strictly adheres to all statutes, court decisions and the opinions of the Texas Attorney General with respect to disclosure of public information under the *Texas Public Information Act*, Chapter 552, *Government Code*.

4.27.6 **Termination.** In addition to any other termination rights set forth in this Agreement and any other rights at law or equity, if University reasonably determines that Contractor has breached any of the restrictions or obligations set forth in this Section, University may immediately terminate this Agreement without notice or opportunity to cure.

4.27.7 **Duration.** The restrictions and obligations under this Section will survive expiration or termination of this Agreement for any reason.

NOTICE TO PROPOSER:

Additional provisions may need to be included to safeguard the security and privacy of data, in compliance with all applicable University and UT System policies on Information Resources Use and Security Policy (ref. Policy UTS165, accessible at

http://www.utsystem.edu/policy/policies/uts165.html and Information Resources Acceptable Use and Security Policy (ref Policy INT124), accessible at http://www.utsystem.edu/policy/policies/int124.html.

4.28 **HIPAA Compliance.** Contractor agrees that it will execute a HIPAA Business Associate Agreement ("BAA") with University and the BAA will be in the form set forth in **APPENDIX SIX**, HIPAA Business Associate Agreement, attached and incorporated for all purposes.

4.29 Default and Termination.

4.29.1 In the event of a material failure by a party to this Agreement to perform in accordance with the terms of this Agreement ("default"), the other party may terminate this Agreement upon fifteen (15) days' written notice of termination setting forth the nature of the material failure; provided, that, the material failure is through no fault of the terminating party. The termination will not be effective if the material failure is fully cured prior to the end of the fifteen-day period.

4.29.2 University may, without cause, terminate this Agreement at any time upon giving seven (7) days' advance written notice to Contractor. Upon termination pursuant to this Section, Contractor will be entitled to payment of an amount that will compensate Contractor for the Services satisfactorily performed from the time of the last payment date to the termination date in accordance with this Agreement; provided, that, Contractor has delivered all Work Material to University.

Notwithstanding any provision in this Agreement to the contrary, University will not be required to pay or reimburse Contractor for any services performed or for expenses incurred by Contractor after the date of the termination notice that could have been avoided or mitigated by Contractor.

- 4.29.3 Termination under **Sections 4.29.1 or 4.29.2** will not relieve Contractor from liability for any default or breach under this Agreement or any other act or omission of Contractor.
- 4.29.4 If Contractor fails to cure any default within fifteen (15) days after receiving written notice of the default, University will be entitled (but will not be obligated) to cure the default and will have the right to offset against all amounts due to Contractor under this Agreement, any and all reasonable expenses incurred in connection with University's curative actions.
- 4.29.5 In the event that this Agreement is terminated, then within thirty (30) days after termination, Contractor will reimburse University for all fees paid by University to Contractor that were (a) not earned by Contractor prior to termination, or (b) for goods or services that University did not receive from Contractor prior to termination.

4.30 Binding Effect

This Agreement will be binding upon and inure to the benefit of the parties hereto and their respective permitted assigns and successors.

4.31 Severability

In case any provision of this Agreement will, for any reason, be held invalid or unenforceable in any respect, the invalidity or unenforceability will not affect any other provision of this Agreement, and this Agreement will be construed as if the invalid or unenforceable provision had not been included.

4.32 Limitation of Liability

EXCEPT FOR UNIVERSITY'S OBLIGATION (IF ANY) TO PAY CONTRACTOR CERTAIN FEES AND EXPENSES UNIVERSITY WILL HAVE NO LIABILITY TO CONTRACTOR OR TO ANYONE CLAIMING THROUGH OR UNDER CONTRACTOR BY REASON OF THE EXECUTION OR PERFORMANCE OF THIS AGREEMENT. NOTWITHSTANDING ANY DUTY OR OBLIGATION OF UNIVERSITY TO CONTRACTOR OR TO ANYONE CLAIMING THROUGH OR UNDER CONTRACTOR, NO PRESENT OR FUTURE AFFILIATED ENTERPRISE, SUBCONTRACTOR, AGENT, OFFICER, DIRECTOR, EMPLOYEE, REPRESENTATIVE, ATTORNEY OR REGENT OF UNIVERSITY, OR THE UNIVERSITY OF TEXAS SYSTEM, OR ANYONE CLAIMING UNDER UNIVERSITY HAS OR WILL HAVE ANY PERSONAL LIABILITY TO CONTRACTOR OR TO ANYONE CLAIMING THROUGH OR UNDER CONTRACTOR BY REASON OF THE EXECUTION OR PERFORMANCE OF THIS AGREEMENT.

4.33 Assignment and Subcontracting

Except as specifically provided in **APPENDIX TWO**, Historically Underutilized Business Subcontracting Plan, attached and incorporated for all purposes, Contractor's interest in this Agreement (including Contractor's duties and obligations under this Agreement, and the fees due to Contractor under this Agreement) may not be subcontracted, assigned, delegated, or otherwise transferred to a third party, in whole or in part, and any attempt to do so will (a) not be binding on University; and (b) be a breach of this Agreement for which

Contractor will be subject to all remedial actions provided by Texas law, including Chapter 2161, *Government Code*, and 34 Texas Administrative Code (“TAC”) Sections 20.101 through 20.108. The benefits and burdens of this Agreement are assignable by University.

4.34 Historically Underutilized Business Subcontracting Plan

Historically Underutilized Business Subcontracting Plan. Contractor agrees to use good faith efforts to subcontract the Services in accordance with the Historically Underutilized Business Subcontracting Plan (“HSP”) (ref. APPENDIX TWO) Contractor agrees to maintain business records documenting its compliance with the HSP and to submit a monthly compliance report to University in the format required by Texas Procurement and Support Services Division of the Texas Comptroller of Public Accounts or any successor agency (collectively, “TPSS”). Submission of compliance reports will be required as a condition for payment under this Agreement. If University determines that Contractor has failed to subcontract as set out in the HSP, University will notify Contractor of any deficiencies and give Contractor an opportunity to submit documentation and explain why the failure to comply with the HSP should not be attributed to a lack of good faith effort by Contractor. If University determines that Contractor failed to implement the HSP in good faith, University, in addition to any other remedies, may report nonperformance to the TPSS in accordance with 34 TAC Sections 20.101 through 20.108. University may also revoke this Agreement for breach and make a claim against Contractor.

4.34.1 Changes to the HSP. If at any time during the term of this Agreement, Contractor desires to change the HSP, before the proposed changes become effective (a) Contractor must comply with 34 TAC Section 20.14; (b) the changes must be reviewed and approved by University; and (c) if University approves changes to the HSP, this Agreement must be amended in accordance with **Section 4.20** to replace the HSP with the revised subcontracting plan.

4.34.2 Expansion of the Services. If University expands the scope of the Services through a change order or any other amendment, University will determine if the additional Services contains probable subcontracting opportunities *not* identified in the initial solicitation for the Services. If University determines additional probable subcontracting opportunities exist, Contractor will submit an amended subcontracting plan covering those opportunities. The amended subcontracting plan must comply with the provisions of 34 TAC Section 20.14 before (a) this Agreement may be amended to include the additional Services; or (b) Contractor may perform the additional Services. If Contractor subcontracts any of the additional subcontracting opportunities identified by University without prior authorization and without complying with 34 TAC Section 20.14, Contractor will be deemed to be in breach of this Agreement under **Section 4.29** and will be subject to any remedial actions provided by Texas law including Chapter 2161, *Government Code* and 34 TAC Section 20.14. University may report nonperformance under this Agreement to the TPSS in accordance with 34 TAC Sections 20.101 through 20.108.

4.35 Responsibility for Individuals Performing Services; Criminal Background Checks.

Each individual who is assigned to perform the Services under this Agreement will be an employee of Contractor or an employee of a subcontractor engaged by Contractor. Contractor is responsible for the performance of all individuals performing the Services under this Agreement. Prior to commencing the Services, Contractor will (1) provide University with a list ("List") of all individuals who may be assigned to perform the Services, and (2) have an appropriate criminal background screening performed on all the individuals. Contractor will determine on a case-by-case basis whether each individual assigned to perform the Services is qualified to provide the services. Contractor will not knowingly assign any individual to provide services on University's campus who has a history of criminal conduct unacceptable for a university campus or healthcare center, including violent or sexual offenses. Contractor will update the List each time there is a change in the individuals assigned to perform the Services.

Prior to commencing performance of the Services under this Agreement, Contractor will provide University a letter signed by an authorized representative of Contractor certifying compliance with this Section. Contractor will provide University an updated certification letter each time there is a change in the individuals assigned to perform the Services.

4.36 Limitations

THE PARTIES ARE AWARE THAT THERE ARE CONSTITUTIONAL AND STATUTORY LIMITATIONS ON THE AUTHORITY OF UNIVERSITY (A STATE AGENCY) TO ENTER INTO CERTAIN TERMS AND CONDITIONS THAT MAY BE A PART OF THIS AGREEMENT, INCLUDING THOSE TERMS AND CONDITIONS RELATING TO LIENS ON UNIVERSITY'S PROPERTY; DISCLAIMERS AND LIMITATIONS OF WARRANTIES; DISCLAIMERS AND LIMITATIONS OF LIABILITY FOR DAMAGES; WAIVERS, DISCLAIMERS AND LIMITATIONS OF LEGAL RIGHTS, REMEDIES, REQUIREMENTS AND PROCESSES; LIMITATIONS OF PERIODS TO BRING LEGAL ACTION; GRANTING CONTROL OF LITIGATION OR SETTLEMENT TO ANOTHER PARTY; LIABILITY FOR ACTS OR OMISSIONS OF THIRD PARTIES; PAYMENT OF ATTORNEYS' FEES; DISPUTE RESOLUTION; INDEMNITIES; AND CONFIDENTIALITY (COLLECTIVELY, THE "LIMITATIONS"), AND TERMS AND CONDITIONS RELATED TO THE LIMITATIONS WILL NOT BE BINDING ON UNIVERSITY EXCEPT TO THE EXTENT AUTHORIZED BY THE LAWS AND CONSTITUTION OF THE STATE OF TEXAS.

4.37 Survival of Provisions

No expiration or termination of this Agreement will relieve either party of any obligations under this Agreement that by their nature survive such expiration or termination.

4.38 Relationship of the Parties

For all purposes of this Agreement and notwithstanding any provision of this Agreement to the contrary, Contractor is an independent contractor and is not a state employee, partner, joint venturer, or agent of University. Contractor will not bind nor attempt to bind University to any agreement or contract. As an independent contractor, Contractor is solely responsible for all taxes, withholdings, and other statutory or contractual obligations of any sort, including workers' compensation insurance.

4.39 State of Texas Computer Equipment Recycling Program Certification.

Pursuant to Section 361.965, *Health and Safety Code*, Contractor certifies that it is full compliance with the *State of Texas Manufacturer Responsibility and Consumer Convenience Computer Equipment Collection and Recovery Act* set forth in Chapter 361, Subchapter Y, *Health and Safety Code*, and the rules adopted by the Texas Commission on Environmental Quality under that Act as set forth in Title 30, Chapter 328, Subchapter I, *Texas Administrative Code*. Contractor acknowledges that this Agreement may be terminated and payment may be withheld if this certification is inaccurate.

4.40 Certifications of Nonsegregated Facilities and Equal Employment Opportunities Compliance

Contractor certifies that, except for restrooms and wash rooms and one (1) or more lactation rooms each of which is segregated on the basis of sex: (1) it does not maintain or provide for its employees any segregated facilities at any of its establishments and that it does not permit its employees to perform their services at any location under its control where segregated facilities are maintained; (2) it will not maintain or provide for its employees any segregated facilities at any of its establishments; and (3) it will not permit its employees to perform their services at any location under its control where segregated facilities are maintained. A breach of this certification is a violation of the Equal Opportunity clause. The term "**segregated facilities**" means any waiting rooms, work areas, rest rooms and wash rooms, entertainment areas, and transportation or housing facilities provided for employees which are segregated by explicit directive or are in fact segregated on the basis of race, color, religion, sex, or national origin, because of habit, local custom, or otherwise. Contractor further agrees that, except where it has contracts prior to the award with subcontractors exceeding \$10,000.00 which are not exempt from the provisions of the Equal Opportunity clause, Contractor will retain the certifications for each one of its subcontractors in Contractor's files, and that it will forward the following notice to all proposed subcontractors (except where the proposed subcontractors have submitted identical certifications for specific time periods):

NOTICE TO PROSPECTIVE SUBCONTRACTORS OF REQUIREMENTS FOR CERTIFICATIONS OF NONSEGREGATED FACILITIES - A Certification on Nonsegregated Facilities must be submitted prior to the award of any subcontract exceeding \$10,000.00 which is not exempt from the provisions of the Equal Opportunity clause. The certification may be submitted either for each subcontract or for all subcontracts during a period (i.e. quarterly, semiannually, or annually).

Contractor understands that the penalty for making false statements regarding the subject matters of this Section is prescribed in 18 U.S.C. 1001.

4.41 Debarment

Contractor confirms that neither Contractor nor its Principals are suspended, debarred, proposed for debarment, declared ineligible, or voluntarily excluded from the award of contracts from United States ("U.S.") federal government procurement or nonprocurement programs, or are listed in the List of Parties Excluded from Federal Procurement or Nonprocurement Programs (<http://www.epls.gov/>) issued by the U.S. General Services Administration. "**Principals**" means officers, directors, owners, partners, and persons having primary management or supervisory responsibilities within a business entity (e.g. general manager, plant manager, head of a subsidiary, division or business segment, and similar positions). Contractor will provide immediate written

notification to University if, at any time prior to award, Contractor learns that this certification was erroneous when submitted or has become erroneous by reason of changed circumstances. This certification is a material representation of fact upon which reliance will be placed when University executes this Agreement. If it is later determined that Contractor knowingly rendered an erroneous certification, in addition to the other remedies available to University, University may terminate this Agreement for default by Contractor.

4.42 Office of Inspector General Certification

Contractor acknowledges that University is prohibited by federal regulations from allowing any employee, representative, agent or subcontractor of Contractor to work on site at University's premises or facilities if that individual is not eligible to work on federal healthcare programs including Medicare, Medicaid, or other similar federal programs. Therefore, Contractor will not assign any employee, representative, agent or subcontractor that appears on the List of Excluded Individuals issued by the United States Office of the Inspector General ("OIG") to work on site at University's premises or facilities. Contractor will perform an OIG sanctions check quarterly on each of its employees, representatives, agents, and subcontractors during the time the employees, representatives, agents, or subcontractors are assigned to work on site at University's premises or facilities. Contractor acknowledges that University will require immediate removal of any employee, representative, agent, or subcontractor of Contractor assigned to work at University's premises or facilities if the employee, representative, agent, or subcontractor is found to be on the OIG's List of Excluded Individuals. The OIG's List of Excluded Individuals may be accessed through the following Internet website:

http://www.oig.hhs.gov/fraud/exclusions/exclusions_list.asp

4.43 Access to Documents

To the extent applicable to this Agreement, in accordance with Section 1861(v)(l)(i) of the Social Security Act (42 U.S.C. 1395x) as amended, and the provisions of 42 CFR Section 420.300, et seq., Contractor will allow, during and for a period of not less than four (4) years after the expiration or termination of this Agreement, access to this Agreement and its books, documents, and records; and contracts between Contractor and its subcontractors or related organizations, including books, documents and records relating to same, by the Comptroller General of the United States, the U.S. Department of Health and Human Services and their duly authorized representatives.

4.44 Placeholder for Further Software-Related Terms that may be appropriate, such as

- **terms of any software licensing that may be required;**
- **roles of Contractor and University (or its contractor) to maintain the software; and**
- **ability to discontinue use of unnecessary modules or functions of any licensed software, with corresponding fee reductions.**

SECTION 5

SPECIFICATIONS AND ADDITIONAL QUESTIONS

5.1 General

The minimum requirements and the specifications for the Services, as well as certain requests for information to be provided by Proposer as part of its proposal, are set forth below. As indicated in **Section 2.3** of this RFP, the successful Proposer is referred to as the “Contractor.”

Restriction on Nature of Expenditures for Clinical Trial Management Technology

The Board of Regents of UT System has appropriated funds for the procurement of technology and services that would enhance the revenue cycle operations of UT System’s medical institutions. Under the Texas Constitution, these appropriated funds, having originated from Permanent University Fund (PUF) bond proceeds, may be used only to fund “capital and equipment items” related to the educational mission of UT System and UT System institutions. As a result, the institutions’ use of the funds to purchase **clinical trial management system** services would not be permitted, since payments under such an arrangement would be characterized as operating expenses, not capital expenditures.

With this background in mind, it may be necessary for Proposer to grant a multi-year license of its software, on the terms outlined below, since this arrangement would help characterize certain expenditures by University as capital in nature. University invites Proposer to offer alternative suggestions for structuring a business relationship with University in ways that would accomplish the objectives of University within the restrictions imposed on use of the appropriated funds. In particular, University would welcome other ideas for qualifying at least some of the costs as “capital” expenditures within the meaning of applicable Government Accounting Standards Board (GASB) rules.

Key Aspects of Proposed Business Relationship

1. University and Proposer would enter into a multi-year agreement for Proposer’s provision of the above-described **clinical trial management system** to University.
2. Proposer would grant to University a multi-year license to use the software for the duration of the agreement.
3. University would pay to Proposer a software license fee, payable in installments according to a formula to be determined, as well as Proposer’s fees and expenses for implementing the software system and developing appropriate interfaces on University’s computers.
4. University would pay to Proposer agreed fees for Proposer’s ongoing maintenance of the software and for technical assistance in operating the software interfaces.
5. **Section 4** and **Section 5** of this RFP summarize other key terms that would apply, including terms governing Proposer’s access to sensitive data during its performance under the agreement (compliance with HIPAA, e.g.); ownership of work material resulting from development work undertaken by Proposer as part of its performance; and Proposer’s compliance with EIR accessibility requirements.

5.2 Minimum Requirements

Each Proposal must include information that clearly indicates that Proposer meets each of the following minimum qualification requirements:

- 5.2.1 CTMS must be web accessible;
- 5.2.2 CTMS must be hosted by the vendor;
- 5.2.3 CTMS contractor must provide implementation configuration, customization, validation and training;
- 5.2.4 CTMS must be 21 CFR Part 11 compliant;
- 5.2.5 CTMS must be capable of tracking study financials at the patient service/clinical charge level
- 5.2.6 CTMS must be able to support processes to apply the Medicare Coverage Analysis according to clinical trial billing rules.

5.3 Additional Questions Specific to this RFP

Proposer must submit the following information as part of Proposer's proposal:

- 5.3.1 In its proposal, Proposer must indicate whether it will consent to include in the Agreement the "Access by Individuals with Disabilities" language that is set forth in **APPENDIX FOUR Access by Individuals with Disabilities**. If Proposer objects to the inclusion of the "Access by Individuals with Disabilities" language in the Agreement, Proposer must, as part of its proposal, specifically identify and describe in detail all of the reasons for Proposer's objection. NOTE THAT A GENERAL OBJECTION IS NOT AN ACCEPTABLE RESPONSE TO THIS QUESTION.
- 5.3.2 In its proposal, Proposer must respond to each item listed in **APPENDIX FIVE, Electronic and Information Resources ("EIR") Environment Specifications**. **APPENDIX FIVE** will establish specifications, representations, warranties and agreements related to the EIR that Proposer is offering to provide to University. Responses to **APPENDIX FIVE** will be incorporated into the Agreement and will be binding on Contractor.
- 5.3.3 If Proposer takes exception to any terms or conditions set forth in **Section 4** of this RFP, or the Business Associate Agreement (**APPENDIX SIX**), Proposer must submit a list of the exceptions.
- 5.3.4 Proposers must provide answers to the questions listed in the Proposer's Questionnaire (**Section 3, APPENDIX ONE**) to the best of Proposer's knowledge, as responses may be incorporated into the Agreement. The questions in the Proposer's Survey will provide UTHSCSA with additional information about Proposer and various efficiencies and economies of scale that Proposer may provide to Institutional Participants.

5.4 Scope of Work

Contractor will provide the following services to University:

- 5.4.1 Leading the process for OCR will be the CTU Director and the following staff: Sr. Financial Analyst, Sr. Contract Analyst and Project Coordinator. The intent of this project is to identify the “common denominators” in the clinical research enterprise processes applicable to a CTMS and create an implementation approach and system model that can satisfy user needs across the enterprise and throughout the life-cycle of a study.
- 5.4.2 The vendor support services for implementation, configuration, validation and training of the CTMS are critical to success. Through the interactions of the vendor consultants with the HSC-CTMS project management team, at a minimum the following deliverables will be developed to ensure optimum setup:
- Implementation Plan and Timeline
 - Validation Plan for System & Hardware
 - Validation Summary Report
 - Training Plan for Implementation
- 5.4.3 The vendor's response must include a plan for the activities described above with estimated costs, timelines and process flow sheets.
- 5.4.4 Simple electronic interfaces between the CTMS and other software systems will be identified and developed during the implementation of the system, but more complex interfaces with other HSC or affiliate systems will be identified and explored for future enhancements as the use of the CTMS ramps up. Possible CTMS electronic interfaces within the HSC include: Peoplesoft, EPIC, EPICARE, Research Profile System, Key Solutions e-Protocol, and Clinical Study Database/web page. Possible affiliate hospital interfaces are with IDX and Sunrise.
- 5.4.5 The table below highlights the CTMS capabilities that are minimally required.

| Basic System Capabilities for all PIs/RTs |
|---|
| <ul style="list-style-type: none">● Track study progress at the study event and patient visit level● Profile patients in the recruiting database● Manage and track patient visits, including; scheduling, screening, information collection, workflow configuration and event reminders● Provide trial oversight through the use of progress reports & dashboards● Allow comprehensive management and workload balancing through reporting of study activities and staff productivity● Professional budget development and negotiations to ensure sufficient study funding● Evaluate and optimize study contract terms● Comprehensive financial management and reporting, including: Invoicing for accounts receivable (AR), bill tracking for accounts payable (AP), accruing earned revenues and reconciliation of milestone and other payments● Adverse Event and Serious Adverse Event management and reporting● Routine safety evaluation of data as collected● Checks for inclusion and exclusion criteria● Regulatory binder document management● Improved communication & reduced paperwork |

- Improves and facilitates workflow through standard practices
- Study level, role-based access and privileges to CTMS functionalities
- Provides compliance to and support for HIPAA, current Good Clinical Practice (cGCP), 21 Code of Federal Regulations (CFR) Part 11, and Quality System Regulations for data security and integrity

- 5.5.6 The multiple objectives of a CTMS implementation must be well understood, e.g.; achieving sound financial practices while also enhancing protocol management and therefore regulatory compliance and patient care issues.
- 5.5.7 Perhaps the most ground-breaking benefit of the centrally managed CTMS is the visibility of CT performance metrics across the entire HSC. Real time and periodic financial performance reports will be available at the study, department, center and enterprise level. Similar reports for study progress and staff activity will also be available thereby, greatly enhancing the ability to strategically manage these key aspects of the institution's research portfolio at an executive level with accurate and detailed data.
- 5.5.8 In addition, the security features of a hosted CTMS application should include:
- Authenticated System Access: All applications require authenticated access to the system using a login identifier and password. Passwords are always encrypted and login identifiers are unique.
 - Password Strength: All passwords are required to be at least 6 characters and must include a combination of alphabetic and numeric characters.
 - Password Aging: All users are required to change their passwords within a customer-specified period of days. 90-day password expiration is the default. Users are warned before the password expires.
 - Inactive Session Termination: The system administrator will designate the amount of time a session can be "inactive" prior to the program automatically terminating. This prevents a situation where a user steps away from his/her desk, inadvertently leaves confidential information visible on their screen.
 - Data Partitioning: meet HIPAA's guidelines for providing user access to data strictly on a "need to know" basis
 - User Activity Auditing: detailed logging of the viewing and/or modification of patient-specific information, along with a list of all successful and failed system login attempts
 - Data encryption- provide assurance that all traffic between the application and users and between the application and the database servers is encrypted using current standards.

SECTION 6 **PRICING AND DELIVERY SCHEDULE**

Proposal of: _____
(Proposer Company Name)

To: The University of Texas at Health Science Center at San Antonio

Ref.: Clinical Trial Management System related to the Office of Clinical Research

RFP No.: **745 – 11 – P04**

Ladies and Gentlemen:

Having carefully examined all the specifications and requirements of this RFP and any attachments thereto, the undersigned proposes to furnish the **Clinical Trial Management System** required pursuant to the above-referenced Request for Proposal upon the terms quoted below.

6.1 Pricing for Services Offered

Please complete the below table. Provide pricing for additional items not listed, using a similar table format.

6.2 Delivery Schedule of Events and Time Periods

Please confirm your acceptance of the delivery schedule noted in the below table. If proposing a different delivery schedule, please provide details using a similar table format.

| Pricing and Delivery Schedule | | | | |
|-------------------------------|-----|---|------|----------------|
| Year | No. | Description of Service | Cost | Delivery Month |
| 1 | 1 | Web accessible, vendor hosted CTMS for up to 25 active studies with 500 active participants. | | 1 |
| | 2 | User documentation - Standard operating procedures | | 1 |
| | 3 | User documentation - Operational guides and tip-sheets | | 1 |
| | 4 | User documentation - Training materials | | 1 |
| | 5 | Training plan and schedule for Implementation training | | 1 |
| | 6 | Formal specification requirements of hardware/software | | 2 |
| | 7 | System configuration for the HSC | | 2 |
| | 8 | Development support regarding CTMS implementation configuration | | 1 - 3 |
| | 9 | HSC Project Team training on the system | | 3 |
| | 10 | Pilot test plan for HSC configuration of CTMS | | 3 |
| | 11 | Formal specification requirements of hardware/software | | 3 |
| | 12 | Design testing to include a traceability matrix (specifications vs. test outcomes) | | 3 |
| | 13 | Installation Qualification and Operational Qualification validation plan for CTMS hardware and software | | 4-6 |

| | | | | |
|---|----|--|--|---------|
| | 14 | Plan for user qualification on CTMS | | 4-6 |
| | 15 | Documentation for user qualification on CTMS | | 4-6 |
| | 16 | Development support regarding CTMS report and object development. | | 3-12 |
| | 17 | Development support regarding CTMS training | | 10 - 12 |
| | 18 | Installation Qualifications and Operational Qualifications report documenting that the CTMS software is installed and configured correctly and functions according to HSC specifications | | 10 - 12 |
| | 19 | Development Support for CTO/CTMS Change Control Procedures | | 10-12 |
| | 20 | One (1) software interface between the CTMS platform and EPIC Billing System to comply with Medicare billing rules. | | 12 |
| 2 | 21 | Web accessible, vendor hosted CTMS for up to 300 active studies with 6,000 active participants. | | 1 |
| | 22 | *Ongoing operational support | | 1-12 |
| 3 | 23 | Web accessible, vendor hosted CTMS for up to 600 active studies with 12,000 active participants. | | 1 |
| | 24 | *Ongoing operational support | | 1-12 |
| 4 | 25 | Web accessible, vendor hosted CTMS for up to 900 active studies with 18,000 active participants. | | 1 |
| | 26 | *Ongoing operational support | | 1-12 |
| 5 | 27 | Web accessible, vendor hosted CTMS for up to 1,100 active studies with 22,000 active participants. | | 1 |
| | 28 | *Ongoing operational support | | 1-12 |
| | | * Please provide an itemized list of services included in ongoing operational support | | |
| | | | | |

6.3 University's Payment Terms

University's standard payment terms for services are "Net 30 days." Proposer agrees that University will be entitled to withhold _____ percent (____%) of the total payment due under the Agreement until after University's acceptance of the final work product. Indicate below the prompt payment discount that Proposer will provide to University:

Prompt Payment Discount: _____% _____days/net 30 days

Respectfully submitted,

Proposer: _____

By: _____
(Authorized Signature for Proposer)

Name: _____

Title: _____

Date: _____

APPENDIX ONE
PROPOSAL REQUIREMENTS

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SECTION 1**GENERAL INFORMATION****1.1 Purpose**

University is soliciting competitive sealed proposals from Proposers having suitable qualifications and experience providing services in accordance with the terms, conditions and requirements set forth in this RFP. This RFP provides sufficient information for interested parties to prepare and submit proposals for consideration by University.

By submitting a proposal, Proposer certifies that it understands this RFP and has full knowledge of the scope, nature, quality, and quantity of the services to be performed, the detailed requirements of the services to be provided, and the conditions under which such services are to be performed. Proposer also certifies that it understands that all costs relating to preparing a response to this RFP will be the sole responsibility of the Proposer.

PROPOSER IS CAUTIONED TO READ THE INFORMATION CONTAINED IN THIS RFP CAREFULLY AND TO SUBMIT A COMPLETE RESPONSE TO ALL REQUIREMENTS AND QUESTIONS AS DIRECTED.

1.2 Inquiries and Interpretations

University may in its sole discretion respond in writing to written inquiries concerning this RFP and mail its response as an Addendum to all parties recorded by University as having received a copy of this RFP. Only University's responses that are made by formal written Addenda will be binding on University. Any verbal responses, written interpretations or clarifications other than Addenda to this RFP will be without legal effect. All Addenda issued by University prior to the Submittal Deadline will be and are hereby incorporated as a part of this RFP for all purposes.

Proposers are required to acknowledge receipt of each Addendum as specified in this Section. The Proposer must acknowledge all Addenda by completing, signing and returning the Addenda Checklist (ref. **Section 4** of APPENDIX ONE). The Addenda Checklist must be received by University prior to the Submittal Deadline and should accompany the Proposer's proposal.

Any interested party that receives this RFP by means other than directly from University is responsible for notifying University that it has received an RFP package, and should provide its name, address, telephone number and FAX number to University, so that if University issues Addenda to this RFP or provides written answers to questions, that information can be provided to such party.

1.3 Public Information

Proposer is hereby notified that University strictly adheres to all statutes, court decisions and the opinions of the Texas Attorney General with respect to disclosure of public information.

University may seek to protect from disclosure all information submitted in response to this RFP until such time as a final agreement is executed.

Upon execution of a final agreement, University will consider all information, documentation, and other materials requested to be submitted in response to this RFP, to be of a non-confidential and non-proprietary nature and, therefore, subject to public disclosure under the *Texas Public Information Act (Government Code, Chapter 552.001, et seq.)*. Proposer will be advised of a request for public information that implicates their materials and will have the opportunity to raise any objections to disclosure to the Texas Attorney General. Certain information may be protected from release under Sections 552.101, 552.110, 552.113, and 552.131, *Government Code*.

1.4 Type of Agreement

Contractor, if any, will be required to enter into a contract with University in a form that (i) includes terms and conditions substantially similar to the terms and conditions set forth in **Section 4** of this RFP, and (ii) is otherwise acceptable to University in all respects (the "Agreement").

1.5 Proposal Evaluation Process

University will select Contractor by using the competitive sealed proposal process described in this Section. University will open the HSP Envelope submitted by a Proposer prior to opening the Proposer's proposal in order to ensure that the Proposer has submitted the number of completed and signed originals of the Proposer's HUB Subcontracting Plan (also called the HSP) that are required by this RFP (ref. **Section 2.5.4** of the RFP.) All proposals submitted by the Submittal Deadline accompanied by the number of completed and signed originals of the HSP that are required by this RFP will be opened publicly to identify the name of each Proposer submitting a proposal. Any proposals that are not submitted by the Submittal Date or that are not accompanied by the number of completed and signed originals of the HSP that are required by this RFP will be rejected by the University as non-responsive due to material failure to comply with advertised specifications. After the opening of the proposals and upon completion of the initial review and evaluation of the proposals, University may invite one or more selected Proposers to participate in oral presentations. University will use commercially reasonable efforts to avoid public disclosure of the contents of a proposal prior to selection of Contractor.

University may make the selection of Contractor on the basis of the proposals initially submitted, without discussion, clarification or modification. In the alternative, University may make the selection of Contractor on the basis of negotiation

with any of the Proposers. In conducting such negotiations, University will avoid disclosing the contents of competing proposals.

At University's sole option and discretion, University may discuss and negotiate all elements of the proposals submitted by selected Proposers within a specified competitive range. For purposes of negotiation, University may establish, after an initial review of the proposals, a competitive range of acceptable or potentially acceptable proposals composed of the highest rated proposal(s). In that event, University will defer further action on proposals not included within the competitive range pending the selection of Contractor; provided, however, University reserves the right to include additional proposals in the competitive range if deemed to be in the best interests of University.

After submission of a proposal but before final selection of Contractor is made, University may permit a Proposer to revise its proposal in order to obtain the Proposer's best and final offer. In that event, representations made by Proposer in its revised proposal, including price and fee quotes, will be binding on Proposer. University will provide each Proposer within the competitive range with an equal opportunity for discussion and revision of its proposal. University is not obligated to select the Proposer offering the most attractive economic terms if that Proposer is not the most advantageous to University overall, as determined by University.

University reserves the right to (a) enter into an agreement for all or any portion of the requirements and specifications set forth in this RFP with one or more Proposers, (b) reject any and all proposals and re-solicit proposals, or (c) reject any and all proposals and temporarily or permanently abandon this selection process, if deemed to be in the best interests of University. Proposer is hereby notified that University will maintain in its files concerning this RFP a written record of the basis upon which a selection, if any, is made by University.

1.6 Proposer's Acceptance of Evaluation Methodology

By submitting a proposal, Proposer acknowledges (1) Proposer's acceptance of [a] the Proposal Evaluation Process (ref. **Section 1.5** of APPENDIX ONE), [b] the Criteria for Selection (ref. **2.3** of this RFP), [c] the Specifications and Additional Questions (ref. **Section 5** of this RFP), [d] the terms and conditions set forth in **Section 4** of this RFP, and [e] all other requirements and specifications set forth in this RFP; and (2) Proposer's recognition that some subjective judgments must be made by University during this RFP process.

1.7 Solicitation for Proposal and Proposal Preparation Costs

Proposer understands and agrees that (1) this RFP is a solicitation for proposals and University has made no representation written or oral that one or more agreements with University will be awarded under this RFP; (2) University issues this RFP predicated on University's anticipated requirements for the Services, and University has made no representation, written or oral, that any particular scope of services will actually be required by University; and (3) Proposer will bear, as its sole risk and responsibility, any cost that arises from Proposer's preparation of a proposal in response to this RFP.

1.8 Proposal Requirements and General Instructions

- 1.8.1 Proposer should carefully read the information contained herein and submit a complete proposal in response to all requirements and questions as directed.
- 1.8.2 Proposals and any other information submitted by Proposer in response to this RFP will become the property of University.
- 1.8.3 University will not provide compensation to Proposer for any expenses incurred by the Proposer for proposal preparation or for demonstrations or oral presentations that may be made by Proposer, unless otherwise expressly agreed in writing. Proposer submits its proposal at its own risk and expense.
- 1.8.4 Proposals that (i) are qualified with conditional clauses; (ii) alter, modify, or revise this RFP in any way; or (iii) contain irregularities of any kind, are subject to disqualification by University, at University's sole discretion.
- 1.8.5 Proposals should be prepared simply and economically, providing a straightforward, concise description of Proposer's ability to meet the requirements and specifications of this RFP. Emphasis should be on completeness, clarity of content, and responsiveness to the requirements and specifications of this RFP.
- 1.8.6 University makes no warranty or guarantee that an award will be made as a result of this RFP. University reserves the right to accept or reject any or all proposals, waive any formalities, procedural requirements, or minor technical inconsistencies, and delete any requirement or specification from this RFP when deemed to be in University's best interest. University reserves the right to seek clarification from any Proposer concerning any item contained in its proposal prior to final selection. Such clarification may be provided by telephone conference or personal meeting with or writing to University, at University's sole discretion. Representations made by Proposer within its proposal will be binding on Proposer.
- 1.8.7 Any proposal that fails to comply with the requirements contained in this RFP may be rejected by University, in University's sole discretion.

1.9 Preparation and Submittal Instructions

1.9.1 Specifications and Additional Questions

Proposals must include responses to the questions in Specifications and Additional Questions (ref. **Section 5** of this RFP). Proposer should reference the item number and repeat the question in its response. In cases where a question does not apply or if unable to respond, Proposer should refer to the item number, repeat the question, and indicate N/A (Not Applicable) or N/R (No Response), as appropriate. Proposer should explain the reason when responding N/A or N/R.

1.9.2 Execution of Offer

Proposer must complete, sign and return the attached Execution of Offer (ref. **Section 2** of **APPENDIX ONE**) as part of its proposal. The Execution of Offer must be signed by a representative of Proposer duly authorized to bind the Proposer to its proposal. Any proposal received without a completed and signed Execution of Offer may be rejected by University, in its sole discretion.

1.9.3 Pricing and Delivery Schedule

Proposer must complete and return the Pricing and Delivery Schedule (ref. **Section 6** of this RFP), as part of its proposal. In the Pricing and Delivery Schedule, the Proposer should describe in detail (a) the total fees for the entire scope of the Services; and (b) the method by which the fees are calculated. The fees must inclusive of all associated costs for delivery, labor, insurance, taxes, overhead, and profit.

University will not recognize or accept any charges or fees to perform the Services that are not specifically stated in the Pricing and Delivery Schedule.

In the Pricing and Delivery Schedule, Proposer should describe each significant phase in the process of providing the Services to University, and the time period within which Proposer proposes to be able to complete each such phase.

1.9.4 Proposer's General Questionnaire

Proposals must include responses to the questions in Proposer's General Questionnaire (ref. **Section 3** of **APPENDIX ONE**). Proposer should reference the item number and repeat the question in its response. In cases where a question does not apply or if unable to respond, Proposer should refer to the item number, repeat the question, and indicate N/A (Not Applicable) or N/R (No Response), as appropriate. Proposer should explain the reason when responding N/A or N/R.

1.9.5 Addenda Checklist

Proposer should acknowledge all Addenda to this RFP (if any) by completing, signing and returning the Addenda Checklist (ref. **Section 4** of **APPENDIX ONE**) as part of its proposal. Any proposal received without a completed and signed Addenda Checklist may be rejected by University, in its sole discretion.

1.9.6 Submission

Proposer should submit all proposal materials enclosed in a sealed envelope, box, or container. The RFP No. (ref. **Section 1.3** of this RFP) and the Submittal Deadline (ref. **Section 2.1** of this RFP) should be clearly shown in the lower left-hand corner on the top surface of the container. In addition, the name and the return address of the Proposer should be clearly visible.

Proposer must also submit the number of originals of the HUB Subcontracting Plan (also called the HSP) as required by this RFP (ref. **Section 2.5** of the RFP.)

Upon Proposer's request and at Proposer's expense, University will return to a Proposer its proposal received after the Submittal Deadline if the proposal is properly identified. University will not under any circumstances consider a proposal that is received after the Submittal Deadline or which is not accompanied by the number of completed and signed originals of the HSP that are required by this RFP.

University will not accept proposals submitted by telephone, proposals submitted by Facsimile ("FAX") transmission, or proposals submitted by electronic transmission (i.e., e-mail) in response to this RFP.

Except as otherwise provided in this RFP, no proposal may be changed, amended, or modified after it has been submitted to University. However, a proposal may be withdrawn and resubmitted at any time prior to the Submittal Deadline. No proposal may be withdrawn after the Submittal Deadline without University's consent, which will be based on Proposer's submittal of a written explanation and documentation evidencing a reason acceptable to University, in University's sole discretion.

By signing the Execution of Offer (ref. **Section 2** of **APPENDIX ONE**) and submitting a proposal, Proposer certifies that any terms, conditions, or documents attached to or referenced in its proposal are applicable to this procurement only to the extent that they (a) do not conflict with the laws of the State of Texas or this RFP and (b) do not place any requirements on University that are not set forth in this RFP or in the Appendices to this RFP. Proposer further certifies that the submission of a proposal is Proposer's good faith intent to enter into an agreement with University as specified herein and that such intent is not contingent upon University's

acceptance or execution of any terms, conditions, or other documents attached to or referenced in Proposer's proposal.

1.9.7 Page Size, Binders, and Dividers

Proposals must be typed on letter-size (8-1/2" x 11") paper, and must be submitted in a binder. Preprinted material should be referenced in the proposal and included as labeled attachments. Sections within a proposal should be divided by tabs for ease of reference.

1.9.8 Table of Contents

Proposals must include a Table of Contents with page number references. The Table of Contents must contain sufficient detail and be organized according to the same format as presented in this RFP, to allow easy reference to the sections of the proposal as well as to any separate attachments (which should be identified in the main Table of Contents). If a Proposer includes supplemental information or non-required attachments with its proposal, this material should be clearly identified in the Table of Contents and organized as a separate section of the proposal.

1.9.9 Pagination

All pages of the proposal should be numbered sequentially in Arabic numerals (1, 2, 3, etc.). Attachments should be numbered or referenced separately.

SECTION 2
EXECUTION OF OFFER

THIS EXECUTION OF OFFER MUST BE COMPLETED, SIGNED AND RETURNED WITH PROPOSER'S PROPOSAL. FAILURE TO COMPLETE, SIGN AND RETURN THIS EXECUTION OF OFFER WITH THE PROPOSER'S PROPOSAL MAY RESULT IN THE REJECTION OF THE PROPOSAL.

- 2.1 By signature hereon, Proposer represents and warrants the following:
- 2.1.1 Proposer acknowledges and agrees that (1) this RFP is a solicitation for a proposal and is not a contract or an offer to contract; (2) the submission of a proposal by Proposer in response to this RFP will not create a contract between University and Proposer; (3) University has made no representation or warranty, written or oral, that one or more contracts with University will be awarded under this RFP; and (4) Proposer will bear, as its sole risk and responsibility, any cost arising from Proposer's preparation of a response to this RFP.
 - 2.1.2 Proposer is a reputable company that is lawfully and regularly engaged in providing the Services.
 - 2.1.3 Proposer has the necessary experience, knowledge, abilities, skills, and resources to perform the Services.
 - 2.1.4 Proposer is aware of, is fully informed about, and is in full compliance with all applicable federal, state and local laws, rules, regulations and ordinances.
 - 2.1.5 Proposer understands (i) the requirements and specifications set forth in this RFP and (ii) the terms and conditions set forth in Section 4 of this RFP, under which Proposer will be required to operate.
 - 2.1.6 If selected by University, Proposer will not delegate any of its duties or responsibilities under this RFP or the Agreement to any sub-contractor, except as expressly provided in the Agreement.
 - 2.1.7 If selected by University, Proposer will maintain any insurance coverage as required by the Agreement during the term thereof.
 - 2.1.8 All statements, information and representations prepared and submitted in response to this RFP are current, complete, true and accurate. Proposer acknowledges that University will rely on such statements, information and representations in selecting Contractor. If selected by University, Proposer will notify University immediately of any material change in any matters with regard to which Proposer has made a statement or representation or provided information.
 - 2.1.9 PROPOSER WILL DEFEND WITH COUNSEL APPROVED BY UNIVERSITY, INDEMNIFY, AND HOLD HARMLESS UNIVERSITY, THE UNIVERSITY OF TEXAS SYSTEM, THE STATE OF TEXAS, AND ALL OF THEIR REGENTS, OFFICERS, AGENTS AND EMPLOYEES, FROM AND AGAINST ALL ACTIONS, SUITS, DEMANDS, COSTS, DAMAGES, LIABILITIES AND OTHER CLAIMS OF ANY NATURE, KIND OR DESCRIPTION, INCLUDING REASONABLE ATTORNEYS' FEES INCURRED IN INVESTIGATING, DEFENDING OR SETTLING ANY OF THE FOREGOING, ARISING OUT OF, CONNECTED WITH, OR RESULTING FROM ANY NEGLIGENT ACTS OR OMISSIONS OR WILLFUL MISCONDUCT OF PROPOSER OR ANY AGENT, EMPLOYEE, SUBCONTRACTOR, OR SUPPLIER OF PROPOSER IN THE EXECUTION OR PERFORMANCE OF ANY CONTRACT OR AGREEMENT RESULTING FROM THIS RFP.
 - 2.1.10 Pursuant to Sections 2107.008 and 2252.903, *Government Code*, any payments owing to Proposer under any contract or agreement resulting from this RFP may be applied directly to any debt or delinquency that Proposer owes the State of Texas or any agency of the State of Texas regardless of when it arises, until such debt or delinquency is paid in full.
- 2.2 By signature hereon, Proposer offers and agrees to furnish the Services to University and comply with all terms, conditions, requirements and specifications set forth in this RFP.
- 2.3 By signature hereon, Proposer affirms that it has not given or offered to give, nor does Proposer intend to give at any time hereafter, any economic opportunity, future employment, gift, loan, gratuity, special discount, trip, favor or service to a public servant in connection with its submitted proposal. Failure to sign this Execution of Offer, or signing with a false statement, may void the submitted proposal or any resulting contracts, and the Proposer may be removed from all proposal lists at University.
- 2.4 By signature hereon, Proposer certifies that it is not currently delinquent in the payment of any taxes due under Chapter 171, *Tax Code*, or that Proposer is exempt from the payment of those taxes, or that Proposer is an out-of-state taxable entity that is not subject to those taxes, whichever is applicable. A false certification will be deemed a material breach of any resulting contract or agreement and, at University's option, may result in termination of any resulting contract or agreement.

- 2.5** By signature hereon, Proposer hereby certifies that neither Proposer nor any firm, corporation, partnership or institution represented by Proposer, or anyone acting for such firm, corporation or institution, has violated the antitrust laws of the State of Texas, codified in Section 15.01, et seq., *Business and Commerce Code*, or the Federal antitrust laws, nor communicated directly or indirectly the proposal made to any competitor or any other person engaged in such line of business.
- 2.6** By signature hereon, Proposer certifies that the individual signing this document and the documents made a part of this RFP, is authorized to sign such documents on behalf of Proposer and to bind Proposer under any agreements and other contractual arrangements that may result from the submission of Proposer's proposal.
- 2.7** By signature hereon, Proposer certifies as follows:
- "Under Section 231.006, *Family Code*, relating to child support, Proposer certifies that the individual or business entity named in the Proposer's proposal is not ineligible to receive the specified contract award and acknowledges that any agreements or other contractual arrangements resulting from this RFP may be terminated if this certification is inaccurate."
- 2.8** By signature hereon, Proposer certifies that (i) no relationship, whether by blood, marriage, business association, capital funding agreement or by any other such kinship or connection exists between the owner of any Proposer that is a sole proprietorship, the officers or directors of any Proposer that is a corporation, the partners of any Proposer that is a partnership, the joint venturers of any Proposer that is a joint venture or the members or managers of any Proposer that is a limited liability company, on one hand, and an employee of any component of The University of Texas System, on the other hand, other than the relationships which have been previously disclosed to University in writing; (ii) Proposer has not been an employee of any component institution of The University of Texas System within the immediate twelve (12) months prior to the Submittal Deadline; and (iii) no person who, in the past four (4) years served as an executive of a state agency was involved with or has any interest in Proposer's proposal or any contract resulting from this RFP (ref. Section 669.003, *Government Code*). All disclosures by Proposer in connection with this certification will be subject to administrative review and approval before University enters into a contract or agreement with Proposer.
- 2.9** By signature hereon, Proposer certifies that in accordance with Section 2155.004, *Government Code*, no compensation has been received for its participation in the preparation of the requirements or specifications for this RFP. In addition, Proposer certifies that an award of a contract to Proposer will not violate Section 2155.006, *Government Code*, prohibiting University from entering into a contract that involves financial participation by a person who, during the previous five years, has been convicted of violating federal law or assessed a penalty in a federal civil or administrative enforcement action in connection with a contract awarded by the federal government for relief, recovery, or reconstruction efforts as a result of Hurricane Rita, Hurricane Katrina, or any other disaster occurring after September 24, 2005. Pursuant to Sections 2155.004 and 2155.006, *Government Code*, Proposer certifies that Proposer is not ineligible to receive the award of or payments under the Agreement and acknowledges that the Agreement may be terminated and payment withheld if these certifications are inaccurate.
- 210** By signature hereon, Proposer certifies its compliance with all federal laws and regulations pertaining to Equal Employment Opportunities and Affirmative Action.
- 211** By signature hereon, Proposer represents and warrants that all products and services offered to University in response to this RFP meet or exceed the safety standards established and promulgated under the Federal Occupational Safety and Health Law (Public Law 91-596) and the *Texas Hazard Communication Act*, Chapter 502, *Health and Safety Code*, and all related regulations in effect or proposed as of the date of this RFP.
- 212** Proposer will and has disclosed, as part of its proposal, any exceptions to the certifications stated in this Execution of Offer. All such disclosures will be subject to administrative review and approval prior to the time University makes an award or enters into any contract or agreement with Proposer.
- 2.13** If Proposer will sell or lease computer equipment to the University under any agreements or other contractual arrangements that may result from the submission of Proposer's proposal then, pursuant to Section 361.965(c), *Health & Safety Code*, Proposer certifies that it is in compliance with the Manufacturer Responsibility and Consumer Convenience Computer Equipment Collection and Recovery Act set forth in Chapter 361, Subchapter Y, *Health & Safety Code* and the rules adopted by the Texas Commission on Environmental Quality under that Act as set forth in Title 30, Chapter 328, Subchapter I, *Texas Administrative Code*. Section 361.952(2), *Health & Safety Code* states that, for purposes of the Manufacturer Responsibility and Consumer Convenience Computer Equipment Collection and Recovery Act, the term "computer equipment" means a desktop or notebook computer and includes a computer monitor or other display device that does not contain a tuner.

214 Proposer should complete the following information:

If Proposer is a Corporation, then State of Incorporation: _____

If Proposer is a Corporation then Proposer's Corporate Charter Number: _____

RFP No.: _____

NOTICE: WITH FEW EXCEPTIONS, INDIVIDUALS ARE ENTITLED ON REQUEST TO BE INFORMED ABOUT THE INFORMATION THAT GOVERNMENTAL BODIES OF THE STATE OF TEXAS COLLECT ABOUT SUCH INDIVIDUALS. UNDER SECTIONS 552.021 AND 552.023, **GOVERNMENT CODE**, INDIVIDUALS ARE ENTITLED TO RECEIVE AND REVIEW SUCH INFORMATION. UNDER SECTION 559.004, **GOVERNMENT CODE**, INDIVIDUALS ARE ENTITLED TO HAVE GOVERNMENTAL BODIES OF THE STATE OF TEXAS CORRECT INFORMATION ABOUT SUCH INDIVIDUALS THAT IS INCORRECT.

Submitted and Certified By:

(Proposer Institution's Name)

(Signature of Duly Authorized Representative)

(Printed Name/Title)

(Date Signed)

(Proposer's Street Address)

(City, State, Zip Code)

(Telephone Number)

(FAX Number)

SECTION 3

PROPOSER'S GENERAL QUESTIONNAIRE

NOTICE: WITH FEW EXCEPTIONS, INDIVIDUALS ARE ENTITLED ON REQUEST TO BE INFORMED ABOUT THE INFORMATION THAT GOVERNMENTAL BODIES OF THE STATE OF TEXAS COLLECT ABOUT SUCH INDIVIDUALS. UNDER SECTIONS 552.021 AND 552.023, GOVERNMENT CODE, INDIVIDUALS ARE ENTITLED TO RECEIVE AND REVIEW SUCH INFORMATION. UNDER SECTION 559.004, GOVERNMENT CODE, INDIVIDUALS ARE ENTITLED TO HAVE GOVERNMENTAL BODIES OF THE STATE OF TEXAS CORRECT INFORMATION ABOUT SUCH INDIVIDUALS THAT IS INCORRECT.

Proposals must include responses to the questions contained in this Proposer's General Questionnaire. Proposer should reference the item number and repeat the question in its response. In cases where a question does not apply or if unable to respond, Proposer should refer to the item number, repeat the question, and indicate N/A (Not Applicable) or N/R (No Response), as appropriate. Proposer will explain the reason when responding N/A or N/R.

3.1 Proposer Profile

3.1.1 Legal name of Proposer company:

Address of principal place of business:

Address of office that would be providing service under the Agreement:

Number of years in Business: _____

State of incorporation: _____

Number of Employees: _____

Annual Revenues Volume: _____

Name of Parent Corporation, if any _____

NOTE: If Proposer is a subsidiary, University prefers to enter into a contract or agreement with the Parent Corporation or to receive assurances of performance from the Parent Corporation.

- 3.1.2 State whether Proposer will provide a copy of its financial statements for the past two (2) years, if requested by University.
- 3.1.3 Proposer will provide a financial rating of the Proposer entity and any related documentation (such as a Dunn and Bradstreet analysis) that indicates the financial stability of Proposer.
- 3.1.4 Is Proposer currently for sale or involved in any transaction to expand or to become acquired by another business entity? If yes, Proposer will explain the expected impact, both in organizational and directional terms.
- 3.1.5 Proposer will provide any details of all past or pending litigation or claims filed against Proposer that would affect its performance under the Agreement with University (if any).
- 3.1.6 Is Proposer currently in default on any loan agreement or financing agreement with any bank, financial institution, or other entity? If yes, Proposer will specify the pertinent date(s), details, circumstances, and describe the current prospects for resolution.
- 3.1.7 Does any relationship exist (whether by family kinship, business association, capital funding agreement, or any other such relationship) between Proposer and any employee of University? If yes, Proposer will explain.
- 3.1.8 Proposer will provide the name and Social Security Number for each person having at least 25% ownership interest in Proposer. This disclosure is mandatory pursuant to Section 231.006, *Family Code*, and will be used for the purpose of determining whether an owner of Proposer with an ownership interest of at least 25% is more

than 30 days delinquent in paying child support. Further disclosure of this information is governed by the *Texas Public Information Act*, Chapter 552, *Government Code*, and other applicable law.

3.2 Approach to Project Services

- 3.2.1 Proposer will provide a statement of the Proposer's service approach and will describe any unique benefits to University from doing business with Proposer. Proposer will briefly describe its approach for each of the required services identified in **Section 5.4 Scope of Work** of this RFP.
- 3.2.2 Proposer will provide an estimate of the earliest starting date for services following execution of the Agreement.
- 3.2.3 Proposer will submit a work plan with key dates and milestones. The work plan should include:
 - 3.2.3.1 Identification of tasks to be performed;
 - 3.2.3.2 Time frames to perform the identified tasks;
 - 3.2.3.3 Project management methodology;
 - 3.2.3.4 Implementation strategy; and
 - 3.2.3.5 The expected time frame in which the services would be implemented.
- 3.2.4 Proposer will describe the types of reports or other written documents Proposer will provide (if any) and the frequency of reporting, if more frequent than required in the RFP. Proposer will include samples of reports and documents if appropriate.

3.3 General Requirements

- 3.3.1 Proposer will provide summary resumes for its proposed key personnel who will be providing services under the Agreement with University, including their specific experiences with similar service projects, and number of years of employment with Proposer.
- 3.3.2 Proposer will describe any difficulties it anticipates in performing its duties under the Agreement with University and how Proposer plans to manage these difficulties. Proposer will describe the assistance it will require from University.

3.4 Service Support

Proposer will describe its service support philosophy, how is it implemented, and how Proposer measures its success in maintaining this philosophy.

3.5 Quality Assurance

Proposer will describe its quality assurance program, its quality requirements, and how they are measured.

3.6 Questions specific to this RFP

3.6.1 REFERENCES

- 3.6.1.1 Please provide five existing customers (please list any healthcare or academic healthcare customers if applicable) of similar size and scope who can be contacted for a reference related to the services subject of this Proposal process. Details should include: - a brief outline of the goods and services provided - number of transactions sent through your software solution on an annual basis - the length of time that the goods and services have been provided - a named contact that can be approached for a reference and their contact details. Reference sites should be comparable to the goods and services required by the Alliance and should be contacted by the Proposer in advance of the Proposal response to ensure that they are available to provide a reference.
- 3.6.1.2 Provide two financial references (1 trade reference and 1 financial institution/bank reference). List should include Company Name, Mailing Address, Telephone Number, FAX Number, Contact Person and Length of Financial Relationship
- 3.6.1.3 Please identify below any clinical trial management system contracts your company has had under contract, which were terminated prior to completion within the last 3 years, if any, including the circumstances surrounding such early termination.
- 3.6.1.4 How long has your company been in this market?

3.6.2 ACCOUNT MANAGEMENT AND SUPPORT SERVICES

- 3.6.2.1 What is the average response time for an account manager(s) to respond to initial requests?
 <1 hour
 <4 hours
 <8 hours
 <24 hours
- 3.6.2.2 Can your company provide Quarterly Business Reviews (QBR) to UTHSCSA?
- 3.6.2.3 Does your company operate a "toll free" customer service support line?
- 3.6.2.4 What is the average call waiting time for telephone customer support?
 Less than 1 minute
 1-2 minutes
 More than 2 minutes
- 3.6.2.5 What are the hours of operations for your company's customer support line?
 8 A.M. – 5 P.M.
 7 A.M. – 7 P.M.
 24/7
- 3.6.2.6 Please detail your company's problem resolution process for customer complaints and concerns. Please include problem escalation process.
- 3.6.2.7 Please outline your proposed account management team including its location and functional role?
- 3.6.2.8 How does your company assess customer satisfaction with the clinical trial management system software?
- 3.6.2.9 Please detail how your company handles technical questions about your company's clinical trial management system software that come through technical support?
- 3.6.2.10 Please provide a copy of your company's standard service level agreement.
- 3.6.2.11 Please describe the types of reports your company's clinical trial management system has. Include the delivery methods available for these reports.
- 3.6.2.12 How long are the reports described above available for access?
 1 day, 1 week, 1 month, >1month, >3 months?
- 3.6.2.13 Personnel Control activities- provide assurance that discipline and structure are a key component of the application hosting organization and influence the control consciousness of its personnel.
- 3.6.2.14 Physical Security- provides assurance that business premises and information systems are protected from unauthorized access, damage and interference.
- 3.6.2.15 Environmental security- provide assurance that critical information technology infrastructure is protected from certain environmental threats.
- 3.6.2.16 Availability- provide reasonable assurance that the CTMS service is available and accessible to its customers
- 3.6.2.17 Operations- provide reasonable assurance that the Operations department identifies and resolves problems affecting the CTMS service or customers in a timely manner.
- 3.6.2.18 Ongoing Security Audit- provide assurance that processes are in place for reviewing and updating security operations on a regular basis.

3.6.3 PRICING

- 3.6.3.1 Will your company fix price per transaction costs at any of the following time intervals?
 6 months, 12 months, 18 months, 24 months, or 36 months
- 3.6.3.2 Does your company have the ability to price the solution proposed under an annual UTHSC Pricing structure that would allow all the UT System Institutions to use the software as needed?
- 3.6.3.3 Are system updates and upgrades included in your company's proposed pricing?
- 3.6.3.4 If not, please provide more details around what are the anticipated costs for UTHSCSA.
- 3.6.3.5 What are the costs associated with adding additional software applications your company offers in conjunction with clinical trial management system software?

3.6.3.6 Will your company offer a tiered pricing structure whereby more solutions implemented at an institution would result in lower pricing for all software tools purchased?

3.6.3.7 If yes, please present your company's proposed tiered pricing structure.

3.6.3.8 Will your company provide initial software training at no cost?

3.6.3.9 If yes, what type of training methods will your company provide at no cost? Check any that apply.

- In person
- Web based
- Group
- Other

3.6.3.10 Would your company be willing to grant UTHSCSA a multi-year license to use your software? If so, on what terms?

3.6.3.11 Please describe any business arrangements, if any, under which existing users of your software or services have been able to characterize as capital expenditures the fees they pay to you?

3.6.3.12 Is there a 1-time initiation or installation charge? If so, what services are included in that fee?

3.6.4 INCENTIVE REBATES

3.6.4.1 Does your company offer incremental sales volume growth rebates if UTHSCSA can get other medical institutions to adopt the use of your company's software?

3.6.4.2 If yes, please describe your company's approach to structuring a sales volume growth rebate.

3.6.5 PAYMENT TERMS

3.6.5.1 Do you offer early payment discounts?

3.6.5.2 If yes, please provide your company's offering for early payment discounts.

3.6.5.3 Please list any payment options which your company is proposing which have not been communicated or disclosed previously.

3.6.6 COMPETITIVE ADVANTAGE

3.6.6.1 Briefly describe your company's advantage in the marketplace. Please provide only information not previously asked or disclosed herein.

3.6.6.2 Please indicate any additional "value added" services or programs not otherwise asked or disclosed herein that should be considered during the evaluation process.

3.6.7 IMPLEMENTATION

3.6.7.1 How does your company feel your clinical trial management system software should be implemented across UTHSCSA?

3.6.7.2 What is the most cost effective way to implement the solution your company listed above?

3.6.7.3 What is the average time frame to successfully implement your company's clinical trial management system software once a contract has been finalized?

3.6.7.4 Do we need a systems integration specialist?

3.6.7.5 What internal IT resources are required?

3.6.8 TECHNOLOGY CAPABILITIES

3.6.8.1 Please list all major medical software system (s) your company's clinical trial management software is compatible with.

3.6.8.2 Does your company's clinical trial management software use Computer Assisted Coding (CAC) technology?

3.6.8.3 If yes, please select the technology used by the clinical trial management system software. Check all that apply.

- Natural language processing (NLP)
- Computer Software used as index

- 3.6.8.4 What is the average time it takes to enter a typical study into your clinical trial management software?
- 3.6.8.5 Please indicate how your company's clinical trial management software will be compliant with the UTHSCSA's requirements by providing a list of all compliance licenses or certifications that have been achieved.
- 3.6.8.6 Is your company's clinical trial management software offered only as a web-based solution, or would you be willing to let UT Institutions host the software on their own computers?
- 3.6.8.7 Does your company's software allow for customization?
- 3.6.8.8 If yes, please provide a brief summary of what rules can be modified and an overview of your company's capabilities in modifying the software?
- 3.6.8.9 Please describe how your company's software will provide for secure transmission of patient information and data if a web based application is utilized by an institution. Please provide your company's data security policy, if applicable.
- 3.6.8.10 Is access to the clinical trial management system software proposed available 27 hours, 7 days a week?
- 3.6.8.11 How does your company believe the pending healthcare reform will impact the use of your company's clinical trial management system software?
- 3.6.8.12 Will your company agree to allow UT institutions to test your company's proposed clinical trial management system software with real study data for demonstration purposes at no cost?
- 3.6.8.13 Does your company's clinical trial management system software have the capacity to maintain multiple CPT, ICD- and HCPCS codes?
- 3.6.8.14 Does your company's clinical trial management system software have the ability to generate appropriate codes for both professional as well as hospital/technical services?

3.6.9 TRAINING

- 3.6.9.1 Describe the educational and training resources your company provides for the clinical trial management system software.
- 3.6.9.2 How much training in the use of your software would be required for UTHSCSA institutional personnel to access your software and process their own data directly, rather than furnishing the data to your company for processing?
- 3.6.9.3 Are these services (training and documentation support) included in the price of your clinical trial management system software?

3.6.10 PRODUCT OVERVIEW

- 3.6.10.1 Please attach a copy of your standard product overview when introducing customers to your company's available solution.
- 3.6.10.2 Please provide some examples of Return on Investment (ROI) analysis that have been proven with using your company's clinical trial management system software?

SECTION 4

ADDENDA CHECKLIST

Proposal of: _____
(Proposer Company Name)

To: The University of Texas Health Science Center at San Antonio

Ref.: Clinical Trial Management System related to the Office of Clinical Research

RFP No.: 745-11-P04

Ladies and Gentlemen:

The undersigned Proposer hereby acknowledges receipt of the following Addenda to the captioned RFP (initial if applicable).

No. 1 _____ No. 2 _____ No. 3 _____ No. 4 _____ No. 5 _____

Respectfully submitted,

Proposer: _____

By: _____
(Authorized Signature for Proposer)

Name: _____

Title: _____

Date: _____

HUB SUBCONTRACTING PLAN FAQ SHEET

- Q:** **WHAT IS A HUB SUBCONTRACTING PLAN? I'VE NEVER HAD TO FILL OUT ONE OF THESE BEFORE.**
- A:** **TEXAS GOVERNMENT CODE 2161 REQUIRES THAT ALL STATE AGENCIES INCLUDE A HUB SUBCONTRACTING PLAN IN CONTRACTS WITH AN EXPECTED VALUE OF \$100,000 OR MORE. AGENCIES ARE REQUIRED TO IDENTIFY PROBABLE AREAS OF SUBCONTRACTING IN THE SCOPE OF THE WORK AS IT'S DEFINED IN THE BID, PROPOSAL OR OTHER EXPRESSION OF INTEREST.**
- Q:** **WHAT HAPPENS IF I DO NOT INCLUDE A COMPLETED HUB SUBCONTRACTING PLAN WITH MY RESPONSE?**
- A:** **IF PROBABLE SUBCONTRACTING HAS BEEN DECLARED BY THE AGENCY AND A COMPLETED HUB SUBCONTRACTING PLAN IS NOT INCLUDED WITH YOUR RESPONSE, YOUR RESPONSE WILL BE DISQUALIFIED AS NOT MEETING ADVERTISED SPECIFICATIONS.**
- Q:** **IF I AM A HUB VENDOR, DO I HAVE TO FILL OUT A HUB SUBCONTRACTING PLAN?**
- A:** **YES!! IF THE AGENCY HAS DECLARED THAT THERE ARE PROBABLE SUBCONTRACTING OPPORTUNITIES IN THE SCOPE OF THE WORK AS IT'S DEFINED IN THE BID OPPORTUNITY, A HUB SUBCONTRACTING PLAN MUST BE COMPLETED AND RETURNED WITH YOUR RESPONSE OR IT WILL BE CONSIDERED AS A MATERIAL FAILURE TO COMPLY WITH ADVERTISED SPECIFICATIONS (TX GOVERNMENT CODE 2161.252 (B)).**
- Q:** **DOES THIS MEAN THAT I AM REQUIRED TO SUBCONTRACT A PORTION OF THE WORK IN ORDER TO BID ON STATE CONTRACTS?**
- A:** **IF YOUR BUSINESS IS NOT ABLE TO COMPLETE THE ENTIRE SCOPE OF THE WORK AS IT'S DEFINED IN THE BID, PROPOSAL OR OTHER EXPRESSION OF INTEREST WITH INTERNAL STAFF AND RESOURCES (STAFF BEING PAID AS W2'S), THEN RESPONDING VENDORS ARE REQUIRED TO MAKE A GOOD FAITH EFFORT TO DO BUSINESS WITH STATE OF TEXAS CERTIFIED HUBS IN ALL AREAS THAT YOU WILL BE SUBCONTRACTING.**
- Q:** **WHAT DOES A GOOD FAITH EFFORT MEAN?**
- A:** **ACCORDING TO TX GOVERNMENT CODE 2161.253 GOOD FAITH EFFORT INCLUDES ALL OF THE FOLLOWING STEPS:**
- DIVIDE THE WORK INTO REASONABLE LOTS ACCORDING TO INDUSTRY STANDARDS AND PRACTICES**
 - PROVIDE WRITTEN NOTIFICATION OF THE SUBCONTRACTING OPPORTUNITY TO A MINIMUM OF 3 STATE OF TEXAS CERTIFIED HUBS**
 - IDENTIFY THE AREA(S) TO BE SUBCONTRACTED AND INCLUDE INFORMATION ON THE SCOPE OF WORK, REQUIREMENTS, CERTIFICATIONS, AND OTHER PERTINENT INFORMATION, AND A CONTACT PERSON WHO CAN ANSWER FURTHER QUESTIONS ABOUT THE SUBCONTRACT OR PROVIDE OTHER VITAL INFORMATION ABOUT THE SUBCONTRACTING OPPORTUNITY**
 - GIVE THE HUB VENDORS NO LESS THAN 5 WORKING DAYS TO RESPOND TO THE PRIME VENDOR PRIOR TO BID CLOSE**
 - PROVIDE WRITTEN NOTIFICATION OF THE SUBCONTRACTING OPPORTUNITY TO MINORITY OR WOMEN TRADE ORGANIZATIONS OR BUSINESS DEVELOPMENT CENTERS.**

- NEGOTIATE WITH RESPONSIVE VENDORS IN GOOD FAITH, NOT DISQUALIFYING A HUB VENDOR, AND PROVIDE WRITTEN JUSTIFICATION OF THE SELECTION PROCESS IF A NON-HUB VENDOR IS SELECTED

Q: WHAT DO I PUT IN SECTION 2 OF THE HUB SUBCONTRACTING PLAN?

A: IDENTIFY THE AREAS OF THE SCOPE OF WORK THAT YOU INTEND TO SUBCONTRACT BY WORD DESCRIPTION AND COMMODITY CODE CLASS AND ITEM SUCH AS PRINTING (966-59), MAIL SORTING (915-58) OR DOCUMENT SHREDDING (966-71), DATA ENTRY SERVICES (920-21), ETC. A FULL LIST OF COMMODITY CODES CAN BE FOUND AT THE FOLLOWING LINK: HTTP://WWW2.CPA.STATE.TX.US/COM_BOOK/INDEX.HTML

Q: WHAT DO I PUT IN SECTION 3 OF THE HUB SUBCONTRACTING PLAN?

A: COPY A PAGE 2 FOR EACH SUBCONTRACTING OPPORTUNITY. IDENTIFY WHICH SUBCONTRACTING OPPORTUNITY YOU LISTED IN SECTION 2.

Q: WHAT DO I PUT IN SECTION 7?

A: LIST THE THREE STATE OF TEXAS CERTIFIED HUB VENDORS YOU NOTIFIED REGARDING THE PORTION OF THE WORK LISTED IN SECTION 3. SPECIFY THEIR VENDOR IDENTIFICATION NUMBER OR FEDERAL EMPLOYER IDENTIFICATION NUMBER, THE DATE YOU PROVIDED NOTICE AND IF YOU RECEIVED A RESPONSE. ALWAYS ATTACH THE SUPPORTING DOCUMENTATION (LETTERS, PHONE LOGS, FAX TRANSMITTALS, E-MAILS ETC) TO YOUR RESPONSE WITH THE HUB SUBCONTRACTING PLAN DEMONSTRATING EVIDENCE OF THE GOOD FAITH EFFORT THAT WAS PERFORMED.

Q: WHAT SHOULD I PUT IN SECTION 8?

A: LIST THE SUBCONTRACTORS YOU SELECTED TO PERFORM THE PORTION OF THE WORK LISTED IN SECTION 3. ALSO YOU MUST SPECIFY THE EXPECTED PERCENTAGE OF WORK TO BE SUBCONTRACTED, THE APPROXIMATE DOLLAR VALUE OF THE SUBCONTRACT AND INDICATE IF THE COMPANY IS TEXAS HUB CERTIFIED OR NOT.

Q: WHAT DO I DO IF I SELECT A NON-HUB VENDOR, WILL MY RESPONSE BE DISQUALIFIED?

A: NO. YOUR RESPONSE WILL NOT BE DISQUALIFIED, BUT YOU MUST INCLUDE A DETAILED WRITTEN JUSTIFICATION OF YOUR SELECTION PROCESS WITH YOUR HUB SUBCONTRACTING PLAN.

Q: I CAN PERFORM THE ENTIRE SCOPE OF WORK WITHOUT SUBCONTRACTING, WHAT DO I DO?

A: COMPLETE SECTION 9, "SELF PERFORMANCE JUSTIFICATION". YOU MUST INCLUDE A WRITTEN DETAILED DESCRIPTION OF HOW YOUR INTERNAL EMPLOYEES (W2'S) ARE ABLE TO COMPLETE THE ENTIRE SCOPE OF WORK WITHOUT SUBCONTRACTING. INCLUDE WITH YOUR HUB SUBCONTRACTING PLAN RESPONSE ANY REQUIRED CERTIFICATES (MICROSOFT PROJECT MANAGER, CISCO CERTIFICATIONS, ETC) OF YOUR STAFF WHO WILL BE PERFORMING THE WORK.

Q: SOMETIMES I USE CONTRACT EMPLOYEES. HOW DOES THE STATE VIEW THEM?

A: IF YOU ARE PAYING CONTRACT EMPLOYEES AS 1099'S, BY STATE DEFINITION, THEY ARE NOT CONSIDERED AS YOU'RE EMPLOYEES.



HUB SUBCONTRACTING PLAN (HSP)

In accordance with Gov't Code §2161.252, the contracting agency has determined that subcontracting opportunities are probable under this contract. Therefore, respondents, including State of Texas certified Historically Underutilized Businesses (HUBs), must complete and submit a State of Texas HUB Subcontracting Plan (HSP) with their solicitation response.

NOTE: Responses that do not include a completed HSP shall be rejected pursuant to Gov't Code §2161.252(b).

The HUB Program promotes equal business opportunities for economically disadvantaged persons to contract with the State of Texas in accordance with the goals specified in the State of Texas Disparity Study. The HUB goals defined in 34 TAC §20.13 are: **11.9 percent for heavy construction other than building contracts, 26.1 percent for all building construction, including general contractors and operative builders contracts, 57.2 percent for all special trade construction contracts, 20 percent for professional services contracts, 33 percent for all other services contracts, and 12.6 percent for commodities contracts.**

- - Agency Special Instructions/Additional Requirements - -

SECTION 1 - RESPONDENT AND SOLICITATION INFORMATION

- a. Respondent (Company) Name: _____ State of Texas VID #: _____
 Point of Contact: _____ Phone #: _____
- b. Is your company a State of Texas certified HUB? - Yes - No
- c. Solicitation #: _____

SECTION 2 - SUBCONTRACTING INTENTIONS

After having divided the contract work into reasonable lots or portions to the extent consistent with prudent industry practices, the respondent must determine what portion(s) of work, including goods or services, will be subcontracted. Note: In accordance with 34 TAC §20.12., a "Subcontractor" means a person who contracts with a vendor to work, to supply commodities, or contribute toward completing work for a governmental entity. Check the appropriate box that identifies your subcontracting intentions:

- Yes, I will be subcontracting portion(s) of the contract.
 (If Yes, in the spaces provided below, list the portions of work you will be subcontracting, and go to page 2.)

- No, I will not be subcontracting any portion of the contract, and will be fulfilling the entire contract with my own resources.
 (If No, complete SECTION 9 and 10.)

| Line Item # - Subcontracting Opportunity Description | Line Item # - Subcontracting Opportunity Description |
|--|--|
| (#1) - | (#11) - |
| (#2) - | (#12) - |
| (#3) - | (#13) - |
| (#4) - | (#14) - |
| (#5) - | (#15) - |
| (#6) - | (#16) - |
| (#7) - | (#17) - |
| (#8) - | (#18) - |
| (#9) - | (#19) - |
| (#10) - | (#20) - |

*If you have more than twenty subcontracting opportunities, a continuation page is available at <http://www.window.state.tx.us/procurement/prog/hub/hub-forms/HUBSubcontractingPlanContinuationPage1.doc>

Enter your company's name here:

Solicitation #: _____

IMPORTANT: You must complete a copy of this page for each of the subcontracting opportunities you listed in SECTION 2. You may photocopy this page or download copies at <http://www.window.state.tx.us/procurement/prog/hub/hub-forms/HUBSubcontractingPlanContinuationPage2.doc>.

SECTION 3 - SUBCONTRACTING OPPORTUNITY

Enter the line item number and description of the subcontracting opportunity you listed in SECTION 2.

Line Item # _____

Description: _____

SECTION 4 - MENTOR-PROTÉGÉ PROGRAM

If respondent is participating as a Mentor in a State of Texas Mentor Protégé Program, submitting their Protégé (Protégé must be a State of Texas certified HUB) as a subcontractor to perform the portion of work (subcontracting opportunity) listed in SECTION 3, constitutes a good faith effort towards that specific portion of work. Will you be subcontracting the portion of work listed in SECTION 3 to your Protégé?

- Yes (If Yes, complete SECTION 8 and 10.) - No / Not Applicable (If No or Not Applicable, go to SECTION 5.)

SECTION 5 - PROFESSIONAL SERVICES CONTRACTS ONLY

This section applies to Professional Services Contracts only. All other contracts go to SECTION 6.

Does your HSP contain subcontracting of 20% or more with HUB(s)?

- Yes (If Yes, complete SECTION 8 and 10.) - No / Not Applicable (If No or Not Applicable, go to SECTION 6.)

In accordance with Gov't Code §2254.004, "Professional Services" means services: (A) within the scope of the practice, as defined by state law of accounting: architecture; landscape architecture; land surveying; medicine; optometry; professional engineering; real estate appraising; or professional nursing; or (B) provided in connection with the professional employment or practice of a person who is licensed or registered as a certified public accountant; an architect; a landscape architect; a land surveyor; a physician, including a surgeon; an optometrist; a professional engineer; a state certified or state licensed real estate appraiser; or a registered nurse.

SECTION 6 - NOTIFICATION OF SUBCONTRACTING OPPORTUNITY

Complying with a, b and c of this section constitutes Good Faith Effort towards the portion of work listed in SECTION 3. After performing the requirements of this section, complete SECTION 7, 8 and 10.

- a. Provide written notification of the subcontracting opportunity listed in SECTION 3 to three (3) or more HUBs. Use the State of Texas' Centralized Master Bidders List (CMBL), found at <http://www2.cpa.state.tx.us/cmb/cmbhub.html>, and its HUB Directory, found at <http://www2.cpa.state.tx.us/cmb/hubonly.html>, to identify available HUBs. Note: Attach supporting documentation (letters, phone logs, fax transmittals, electronic mail, etc.) demonstrating evidence of the good faith effort performed.
- b. Provide written notification of the subcontracting opportunity listed in SECTION 3 to a minority or women trade organization or development center to assist in identifying potential HUBs by disseminating the subcontracting opportunity to their members/participants. A list of trade organizations and development centers may be accessed at <http://www.window.state.tx.us/procurement/prog/hub/mwb-links-1/>. Note: Attach supporting documentation (letters, phone logs, fax transmittals, electronic mail, etc.) demonstrating evidence of the good faith effort performed.
- c. Written notifications should include the scope of the work, information regarding the location to review plans and specifications, bonding and insurance requirements, required qualifications, and identify a contact person. Unless the contracting agency has specified a different time period, you must allow the HUBs no less than five (5) working days from their receipt of notice to respond, and provide notice of your subcontracting opportunity to a minority or women trade organization or development center no less than five (5) working days prior to the submission of your response to the contracting agency.

SECTION 7 - HUB FIRMS CONTACTED FOR SUBCONTRACTING OPPORTUNITY

List three (3) State of Texas certified HUBs you notified regarding the portion of work (subcontracting opportunity) listed in SECTION 3. Specify the vendor ID number, date you provided notice, and if you received a response. Note: Attach supporting documentation (letters, phone logs, fax transmittals, electronic mail, etc.) demonstrating evidence of the good faith effort performed.

| Company Name | VID # | Notice Date (mm/dd/yyyy) | Was Response Received? |
|--------------|-------|-----------------------------|--|
| _____ | _____ | / / | <input type="checkbox"/> - Yes <input type="checkbox"/> - No |
| _____ | _____ | / / | <input type="checkbox"/> - Yes <input type="checkbox"/> - No |
| _____ | _____ | / / | <input type="checkbox"/> - Yes <input type="checkbox"/> - No |

SECTION 8 - SUBCONTRACTOR SELECTION

List the subcontractor(s) you selected to perform the portion of work (subcontracting opportunity) listed in SECTION 3. Also, specify the expected percentage of work to be subcontracted, the approximate dollar value of the work to be subcontracted, and indicate if the company is a Texas certified HUB.

| Company Name | VID # | Expected % of Contract | Approximate Dollar Amount | Texas Certified HUB? |
|--------------|-------|---------------------------|------------------------------|---|
| _____ | _____ | % | \$ | <input type="checkbox"/> - Yes <input type="checkbox"/> - No* |
| _____ | _____ | % | \$ | <input type="checkbox"/> - Yes <input type="checkbox"/> - No* |

*If the subcontractor(s) you selected is not a Texas certified HUB, provide written justification of your selection process below:

Enter your company's name here: _____ Solitation #: _____

SECTION 9 - SELF PERFORMANCE JUSTIFICATION

(If you responded "No" to SECTION 2, you must complete SECTION 9 and 10.)

Does your response/proposal contain an explanation demonstrating how your company will fulfill the entire contract with its own resources?

- Yes If Yes, in the space provided below, list the specific page/section of your proposal which identifies how your company will perform the entire contract with its own equipment, supplies, materials and/or employees.

- No If No, in the space provided below, explain how your company will perform the entire contract with its own equipment, supplies, materials, and/or employees.

SECTION 10 - AFFIRMATION

As evidenced by my signature below, I affirm that I am an authorized representative of the respondent listed in SECTION 1, and that the information and supporting documentation submitted with the HSP are true and correct. Respondent understands and agrees that, if awarded any portion of the solicitation:

- The respondent must submit monthly compliance reports (Prime Contractor Progress Assessment Report – PAR) to the contracting agency, verifying their compliance with the HSP, including the use/expenditures they have made to subcontractors. (The PAR is available at <http://www.window.state.tx.us/procurement/prog/hub/hub-forms/progressassessmentrpt.xls>).
 - The respondent must seek approval from the contracting agency prior to making any modifications to their HSP. If the HSP is modified without the contracting agency's prior approval, respondent may be subject to debarment pursuant to Gov't Code §2161.253(d).
 - The respondent must, upon request, allow the contracting agency to perform on-site reviews of the company's headquarters and/or work-site where services are to be performed and must provide documents regarding staff and other resources.

Signature

Printed Name

Title

Date

Enter your company's name here: _____

Solicitation #: _____

SECTION 2 | Development of a HSP and Subcontracting Intentions

In the spaces below, continue to list the portions of work (subcontracting opportunities) you intend to subcontract. For each subcontracting opportunity you list, you must demonstrate evidence of Good Faith Effort in developing your HSP by complying with the requirements outlined in the Good Faith Effort Confirmation form (Page 2).

| Line Item # - Subcontracting Opportunity Description | Line Item # - Subcontracting Opportunity Description |
|--|--|
| (#21) - | (#61) - |
| (#22) - | (#62) - |
| (#23) - | (#63) - |
| (#24) - | (#64) - |
| (#25) - | (#65) - |
| (#26) - | (#66) - |
| (#27) - | (#67) - |
| (#28) - | (#68) - |
| (#29) - | (#69) - |
| (#30) - | (#70) - |
| (#31) - | (#71) - |
| (#32) - | (#72) - |
| (#33) - | (#73) - |
| (#34) - | (#74) - |
| (#35) - | (#75) - |
| (#36) - | (#76) - |
| (#37) - | (#77) - |
| (#38) - | (#78) - |
| (#39) - | (#79) - |
| (#40) - | (#80) - |
| (#41) - | (#81) - |
| (#42) - | (#82) - |
| (#43) - | (#83) - |
| (#44) - | (#84) - |
| (#45) - | (#85) - |
| (#46) - | (#86) - |
| (#47) - | (#87) - |
| (#48) - | (#88) - |
| (#49) - | (#89) - |
| (#50) - | (#90) - |
| (#51) - | (#91) - |
| (#52) - | (#92) - |
| (#53) - | (#93) - |
| (#54) - | (#94) - |
| (#55) - | (#95) - |
| (#56) - | (#96) - |
| (#57) - | (#97) - |
| (#58) - | (#98) - |
| (#59) - | (#99) - |
| (#60) - | (#100) - |



HUB Subcontracting Plan (HSP)

Prime Contractor Progress Assessment Report

This form must be completed and submitted to the contracting agency each month to document compliance with your HSP.

Signature: _____

Title: _____

Date: _____

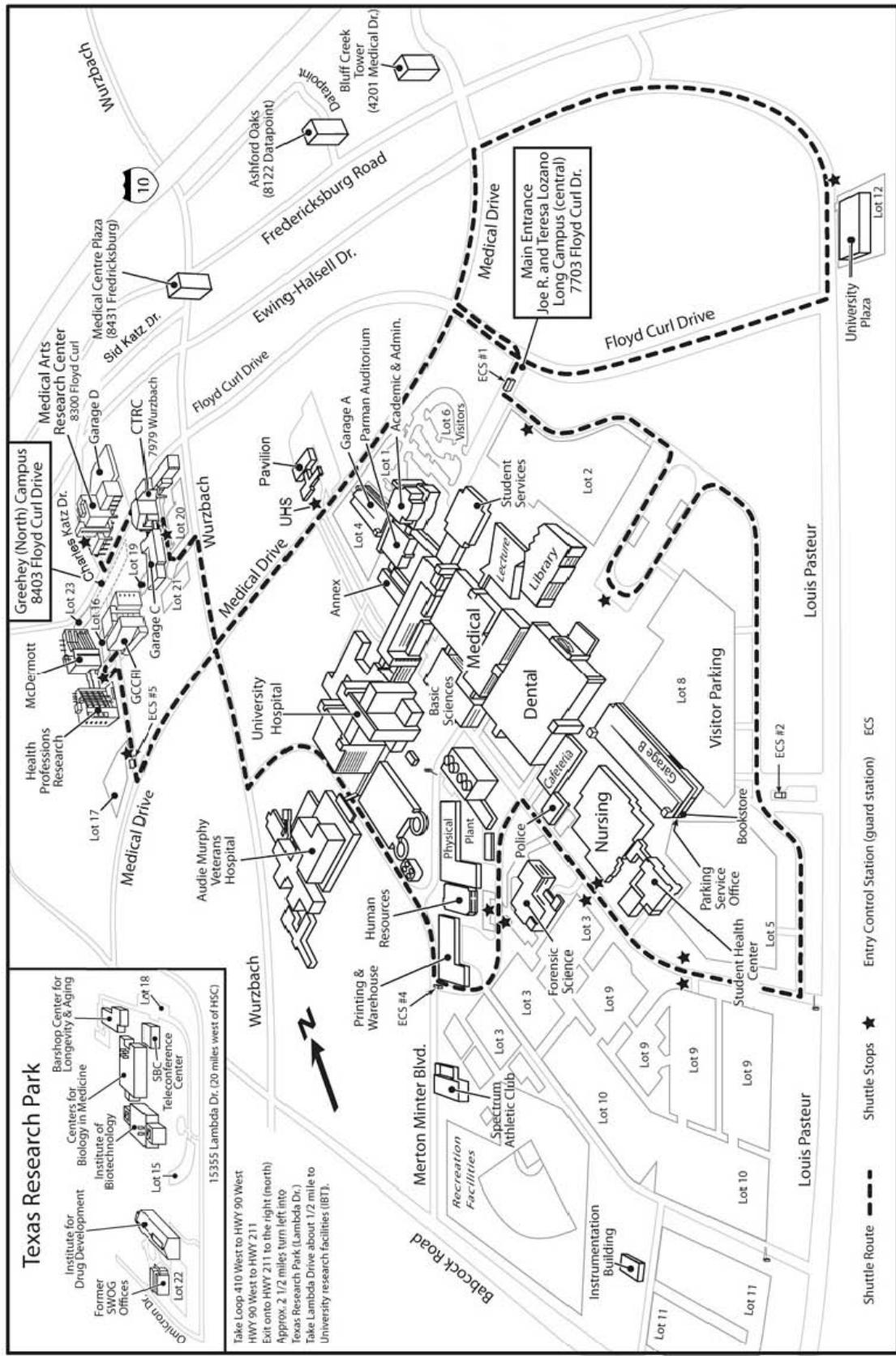
⁷Note: HUB certification status can be verified on-line at: <http://www2.cpa.state.tx.us/cmbl/hubonly.html>



Campus Map

**APPENDIX THREE
CAMPUS MAP**

Pre-Proposal Conference: The University will hold a pre-proposal conference at 1:00 p.m., Central Prevailing Time on **Tuesday, November 9, 2010**, in Room 104 AAB of the Academics and Administration Building.



APPENDIX FOUR

ACCESS BY INDIVIDUALS WITH DISABILITIES

Access by Individuals with Disabilities. Contractor represents and warrants ("EIR Accessibility Warranty") that the electronic and information resources and all associated information, documentation, and support that it provides to the University under this Agreement (collectively, the "EIRs") comply with the applicable requirements set forth in Title 1, Chapter 213, *Texas Administrative Code* and Title 1, Chapter 206, Rule §206.70, *Texas Administrative Code* (as authorized by Chapter 2054, Subchapter M, *Government Code*.) To the extent Contractor becomes aware that the EIRs, or any portion thereof, do not comply with the EIR Accessibility Warranty, then Contractor represents and warrants that it will, at no cost to University, either (1) perform all necessary remediation to make the EIRs satisfy the EIR Accessibility Warranty or (2) replace the EIRs with new EIRs that satisfy the EIR Accessibility Warranty. In the event that Contractor is unable to do so, then the University may terminate this Agreement and Contractor will refund to the University all amounts the University has paid under this Agreement within thirty (30) days after the termination date.

APPENDIX FIVE

ELECTRONIC AND INFORMATION RESOURCE ENVIRONMENT SPECIFICATIONS

The specifications, representations, warranties and agreements set forth in Proposer's responses to this **APPENDIX SIX** will be incorporated into the Agreement.

Basic Specifications

1. If the EIR will be hosted by University, please describe the overall environment requirements for the EIR (size the requirements to support the number of concurrent users, the number of licenses and the input/output generated by the application as requested in the application requirements).
 - A. Hardware: If Proposer will provide hardware, does the hardware have multiple hard drives utilizing a redundant RAID configuration for fault tolerance? Are redundant servers included as well?
 - B. Operating System and Version:
 - C. Web Server: Is a web server required? If so, what web application is required (Apache or IIS)? What version? Are add-ins required?
 - D. Application Server:
 - E. Database:
 - F. Other Requirements: Are any other hardware or software components required?
 - G. Assumptions: List any assumptions made as part of the identification of these environment requirements.
 - H. Storage: What are the space/storage requirements of this implementation?
 - I. Users: What is the maximum number of users this configuration will support?
 - J. Clustering: How does the EIR handle clustering over multiple servers?
 - K. Virtual Server Environment: Can the EIR be run in a virtual server environment?
2. If the EIR will be hosted by Proposer, describe in detail what the hosted solution includes, and address, specifically, the following issues:
 1. Describe the audit standards of the physical security of the facility; and
 2. Indicate whether Proposer is willing to allow an audit by University or its representative.
3. If the user and administrative interfaces for the EIR are web-based, do the interfaces support Firefox on Mac as well as Windows and Safari on the Macintosh?
4. If the EIR requires special client software, what are the environment requirements for that client software?
5. Manpower Requirements: Who will operate and maintain the EIR? Will additional University full time employees (FTEs) be required? Will special training on the EIR be required by Proposer's technical staff? What is the estimated cost of required training?

6. Upgrades and Patches: Describe Proposer's strategy regarding EIR upgrades and patches for both the server and, if applicable, the client software. Included Proposer's typical release schedule, recommended processes, estimated outage and plans for next version/major upgrade.

Security

1. Has the EIR been tested for application security vulnerabilities? For example, has the EIR been evaluated against the Open Web Application Security Project ("OWASP") Top 10 list that includes flaws like cross site scripting and SQL injection? If so, please provide the scan results and specify the tool used. University will not take final delivery of the EIR if University determines there are serious vulnerabilities within the EIR.
2. Which party, Proposer or University, will be responsible for maintaining critical EIR application security updates?
3. If the EIR is hosted, indicate whether Proposer's will permit University to conduct a penetration test on University's instance of the EIR.
4. If confidential data, including HIPAA or FERPA data, is stored in the EIR, will the data be encrypted at rest and in transmittal?

Integration

5. Is the EIR authentication Security Assertion Markup Language ("SAML") compliant? Has Proposer ever implemented the EIR with Shibboleth authentication? If not, does the EIR integrate with Active Directory? Does the EIR support SSL connections to this directory service?
6. Does the EIR rely on Active Directory for group management and authorization or does the EIR maintain a local authorization/group database?
7. What logging capabilities does the EIR have? If this is a hosted EIR solution, will University have access to implement logging with University's standard logging and monitoring tools, RSA's Envision?
8. Does the EIR have an application programming interface ("API") that enables us to incorporate it with other applications run by the University? If so, is the API .Net based? Web Services-based? Other?
9. Will University have access to the EIR source code? If so, will the EIR license permit University to make modifications to the source code? Will University's modifications be protected in future upgrades?
10. Will Proposer place the EIR source code in escrow with an escrow agent so that if Proposer is no longer in business or Proposer has discontinued support, the EIR source code will be available to University?

Accessibility Information

11. Please complete the Voluntary Product Accessibility Template (“**VPAT**”) found at <http://www.itic.org/index.php?submenu=resources&src=gendocs&ref=vpat&category=resources> and submit the VPAT with Proposer’s proposal.

APPENDIX SIX

Sample Business Associate Agreement Provisions

This Business Associate Agreement (the “Agreement”), is made as of the ____ day of _____, 20____ (the “Effective Date”), by and between Business Associate and Covered Entity (collectively the “Parties”) to comply with privacy standards adopted by the U.S. Department of Health and Human Services as they may be amended from time to time, 45 C.F.R. parts 160 and 164, subparts A and E (“the Privacy Rule”) and security standards adopted by the U.S. Department of Health and Human Services as they may be amended from time to time, 45 C.F.R. parts 160, 162 and 164, subpart C (“the Security Rule”) and any applicable state confidentiality laws.

RECITALS

WHEREAS, Business Associate provides a web hosted clinical trial management application, along with vendor implementation support and training to or on behalf of Covered Entity;

WHEREAS, in connection with these services, Covered Entity discloses to Business Associate certain protected health information that is subject to protection under the Privacy Rule; and

WHEREAS, the Privacy Rule requires that Covered Entity receive adequate assurances that Business Associate will comply with certain obligations with respect to the PHI received in the course of providing services to or on behalf of Covered Entity.

NOW THEREFORE, in consideration of the mutual promises and covenants herein, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree as follows:

A. Definitions. Terms used herein, but not otherwise defined, shall have meaning ascribed by the Privacy Rule and the Security Rule.

1. Business Associate. “Business Associate” shall mean [insert name of Business Associate].
2. Covered Entity. “Covered Entity” shall mean The University of Texas Health Science Center at San Antonio.
3. Designated Record Set. “Designated Record Set” shall mean a group of records maintained by or for a Covered Entity that is: (i) the medical records and billing records about Individuals maintained by or for a covered health care provider; (ii) the enrollment, payment, claims adjudication, and case or medical management record systems maintained by or for a health plan; or (iii) used, in whole or in part, by or for the covered entity to make decisions about Individuals. For purposes of this definition, the term “record” means any item, collection, or grouping of information that includes protected health information and is maintained, collected, used, or disseminated by or for a covered entity.

4. **HIPAA Rules.** The Privacy Rule and the Security Rule are referred to collectively herein as “HIPAA Rules.”
 5. **Individual.** “Individual” shall mean the person who is the subject of the protected health information.
 6. **Protected Health Information (“PHI”).** “Protected Health Information” or PHI shall mean individually identifiable health information that is transmitted or maintained in any form or medium.
 7. **Required by Law.** “Required by Law” shall mean a mandate contained in law that compels a use or disclosure of PHI.
 8. **Secretary.** “Secretary” shall mean the Secretary of the Department of Health and Human Services or his or her Designee.
- B. **Purposes for which PHI May Be Disclosed to Business Associate.** In connection with the services provided by Business Associate to or on behalf of Covered Entity described in this Agreement, Covered Entity may disclose PHI to Business Associate for the purposes of **configuring, customizing and validating a web hosted software application; training and operational support for application users; and management and storage of application user data.**
- C. **Obligations of Covered Entity.** If deemed applicable by Covered Entity, Covered Entity shall:
1. provide Business Associate a copy of its Notice of Privacy Practices (“Notice”) produced by Covered Entity in accordance with 45 C.F.R. 164.520 as well as any changes to such Notice;
 2. provide Business Associate with any changes in, or revocation of, authorizations by Individuals relating to the use and/or disclosure of PHI, if such changes affect Business Associate’s permitted or required uses and/or disclosures;
 3. notify Business Associate of any restriction to the use and/or disclosure of PHI to which Covered Entity has agreed in accordance with 45 C.F.R. 164.522;
 4. notify Business Associate of any amendment to PHI to which Covered Entity has agreed that affects a Designated Record Set maintained by Business Associate; and
 5. if Business Associate maintains a Designated Record Set, provide Business Associate with a copy of its policies and procedures related to an Individual’s right to: access PHI; request an amendment to PHI; request confidential communications of PHI; or request an accounting of disclosures of PHI.
- D. **Obligations of Business Associate.** Business Associate agrees to comply with applicable federal and state confidentiality and security laws, specifically the provisions of the

Privacy Rule applicable to business associates (as defined by the Privacy Rule), including:

1. **Use and Disclosure of PHI.** Except as otherwise permitted by this Agreement or applicable law, Business Associate shall not use or disclose PHI except as necessary to provide a **web hosted clinical trial management application, along with vendor implementation support and training** services to or on behalf of Covered Entity, and shall not use or disclose PHI that would violate the HIPAA Rules if used or disclosed by Covered Entity. Provided, however, Business Associate may use and disclose PHI as necessary for the proper management and administration of Business Associate, or to carry out its legal responsibilities. Business Associate shall in such cases:
 - (a) provide information to members of its workforce using or disclosing PHI regarding the confidentiality requirements of the Privacy Rule and this Agreement;
 - (b) obtain reasonable assurances from the person or entity to whom the PHI is disclosed that: (a) the PHI will be held confidential and further used and disclosed only as Required by Law or for the purpose for which it was disclosed to the person or entity; and (b) the person or entity will notify Business Associate of any instances of which it is aware in which confidentiality of the PHI has been breached; and
 - (c) agree to notify the designated Privacy Officer of Covered Entity of any instances of which it is aware in which the PHI is used or disclosed for a purpose that is not otherwise provided for in this Agreement or for a purpose not expressly permitted by the HIPAA Rules.
2. **Data Aggregation.** In the event that Business Associate works for more than one Covered Entity, Business Associate is permitted to use and disclose PHI for data aggregation purposes, however, only in order to analyze data for permitted health care operations, and only to the extent that such use is permitted under the Privacy Rule.
3. **De-identified Information.** Business Associate may use and disclose de-identified health information if (i) the use is disclosed to Covered Entity and permitted by Covered Entity in its sole discretion and (ii) the de-identification is in compliance with 45 C.F.R. §164.502(d), and the de-identified health information meets the standard and implementation specifications for de-identification under 45 C.F.R. §164.514(a) and (b).
4. **Safeguards.** Business Associate shall maintain appropriate safeguards to ensure that PHI is not used or disclosed other than as provided by this Agreement or as Required by Law. Business Associate shall implement administrative, physical and technical safeguards that reasonably and appropriately protect the

confidentiality, integrity, and availability of any electronic PHI it creates, receives, maintains, or transmits on behalf of Covered Entity.

5. **Minimum Necessary.** Business Associate shall attempt to ensure that all uses and disclosures of PHI are subject to the principle of “minimum necessary use and disclosure,” i.e., that only PHI that is the minimum necessary to accomplish the intended purpose of the use, disclosure, or request is used or disclosed.
6. **Disclosure to Agents and Subcontractors.** If Business Associate discloses PHI received from Covered Entity, or created or received by Business Associate on behalf of Covered Entity, to agents, including a subcontractor, Business Associate shall require the agent or subcontractor to agree to the same restrictions and conditions as apply to Business Associate under this Agreement. Business Associate shall ensure that any agent, including a subcontractor, agrees to implement reasonable and appropriate safeguards to protect the confidentiality, integrity, and availability of the electronic PHI that it creates, receives, maintains, or transmits on behalf of the Covered Entity. Business Associate shall be liable to Covered Entity for any acts, failures or omissions of the agent or subcontractor in providing the services as if they were Business Associate’s own acts, failures or omissions, to the extent permitted by law. Business Associate further expressly warrants that its agents or subcontractors will be specifically advised of, and will comply in all respects with, the terms of this Agreement.
7. **Individual Rights Regarding Designated Record Sets.** If Business Associate maintains a Designated Record Set on behalf of Covered Entity Business Associate agrees as follows:
 - (a) **Individual Right to Copy or Inspection.** Business Associate agrees that if it maintains a Designated Record Set for Covered Entity that is not maintained by Covered Entity, it will permit an Individual to inspect or copy PHI about the Individual in that set as directed by Covered Entity to meet the requirements of 45 C.F.R. § 164.524. Under the Privacy Rule, Covered Entity is required to take action on such requests as soon as possible, but not later than 30 days following receipt of the request. Business Associate agrees to make reasonable efforts to assist Covered Entity in meeting this deadline. The information shall be provided in the form or format requested if it is readily producible in such form or format; or in summary, if the Individual has agreed in advance to accept the information in summary form. A reasonable, cost-based fee for copying health information may be charged. If Covered Entity maintains the requested records, Covered Entity, rather than Business Associate shall permit access according to its policies and procedures implementing the Privacy Rule.
 - (b) **Individual Right to Amendment.** Business Associate agrees, if it maintains PHI in a Designated Record Set, to make amendments to PHI at the request and direction of Covered Entity pursuant to 45 C.F.R. 164.526.

If Business Associate maintains a record in a Designated Record Set that is not also maintained by Covered Entity, Business Associate agrees that it will accommodate an Individual's request to amend PHI only in conjunction with a determination by Covered Entity that the amendment is appropriate according to 45 C.F.R. § 164.526.

- (c) Accounting of Disclosures. Business Associate agrees to maintain documentation of the information required to provide an accounting of disclosures of PHI in accordance with 45 C.F.R. § 164.528, and to make this information available to Covered Entity upon Covered Entity's request, in order to allow Covered Entity to respond to an Individual's request for accounting of disclosures. Under the Privacy Rule, Covered Entity is required to take action on such requests as soon as possible but not later than 60 days following receipt of the request. Business Associate agrees to use its best efforts to assist Covered Entity in meeting this deadline. Such accounting must be provided without cost to the individual or Covered Entity if it is the first accounting requested by an individual within any 12 month period; however, a reasonable, cost-based fee may be charged for subsequent accountings if Business Associate informs the individual in advance of the fee and is afforded an opportunity to withdraw or modify the request. Such accounting is limited to disclosures that were made in the six (6) years prior to the request (not including disclosures prior to the compliance date of the Privacy Rule) and shall be provided for as long as Business Associate maintains the PHI.
8. Internal Practices, Policies and Procedures. Except as otherwise specified herein, Business Associate shall make available its internal practices, policies and procedures relating to the use and disclosure of PHI, received from or on behalf of Covered Entity to the Secretary or his or her agents for the purpose of determining Covered Entity's compliance with the HIPAA Rules, or any other health oversight agency, or to Covered Entity. Records requested that are not protected by an applicable legal privilege will be made available in the time and manner specified by Covered Entity or the Secretary.
9. Notice of Privacy Practices. Business Associate shall abide by the limitations of Covered Entity's Notice of which it has knowledge. Any use or disclosure permitted by this Agreement may be amended by changes to Covered Entity's Notice; provided, however, that the amended Notice shall not affect permitted uses and disclosures on which Business Associate relied prior to receiving notice of such amended Notice.
10. Withdrawal of Authorization. If the use or disclosure of PHI in this Agreement is based upon an Individual's specific authorization for the use or disclosure of his or her PHI, and the Individual revokes such authorization, the effective date of such authorization has expired, or such authorization is found to be defective in any manner that renders it invalid, Business Associate shall, if it has notice of such revocation, expiration, or invalidity, cease the use and disclosure of the

Individual's PHI except to the extent it has relied on such use or disclosure, or if an exception under the Privacy Rule expressly applies.

11. Knowledge of HIPAA Rules. Business Associate agrees to review and understand the HIPAA Rules as it applies to Business Associate, and to comply with the applicable requirements of the HIPAA Rule, as well as any applicable amendments.
12. Security Incident. Business Associate agrees to immediately report to the Covered Entity any security incident of which Business Associate becomes aware.

E. Term and Termination.

1. Term. This Agreement shall be effective as of the Effective Date and shall be terminated when all PHI provided to Business Associate by Covered Entity, or created or received by Business Associate on behalf of Covered Entity, is destroyed or returned to Covered Entity.
2. Termination for Breach. If Business Associate breaches any provision in this Agreement, Covered Entity may, at its option, access and audit the records of Business Associate related to its use and disclosure of PHI, require Business Associate to submit to monitoring and reporting, and such other conditions as Covered Entity may determine is necessary to ensure compliance with this Agreement, or Covered Entity may terminate this Agreement on a date specified by Covered Entity.
3. Effect of Termination. Upon termination of this Agreement for any reason, Business Associate agrees to return or destroy all PHI received from Covered Entity, or created or received by Business Associate on behalf of Covered Entity, maintained by Business Associate in any form. If Business Associate determines that the return or destruction of PHI is not feasible, Business Associate shall inform Covered Entity in writing of the reason thereof, and shall agree to extend the protections of this Agreement to such PHI and limit further uses and disclosures of the PHI to those purposes that make the return or destruction of the PHI not feasible for so long as Business Associate retains the PHI.

F. Miscellaneous.

1. Indemnification. To the extent permitted by law, Business Associate agrees to indemnify and hold harmless Covered Entity from and against all claims, demands, liabilities, judgments or causes of action of any nature for any relief, elements of recovery or damages recognized by law (including, without limitation, attorney's fees, defense costs, and equitable relief), for any damage or loss incurred by Covered Entity arising out of, resulting from, or attributable to any acts or omissions or other conduct of Business Associate or its agents in connection with the performance of Business Associate's or its agents' duties under this Agreement. This indemnity shall apply even if Covered Entity is

alleged to be solely or jointly negligent or otherwise solely or jointly at fault; provided, however, that a trier of fact finds Covered Entity not to be solely or jointly negligent or otherwise solely or jointly at fault. This indemnity shall not be construed to limit Covered Entity's rights, if any, to common law indemnity.

Covered Entity shall have the option, at its sole discretion, to employ attorneys selected by it to defend any such action, the costs and expenses of which shall be the responsibility of Business Associate. Covered Entity shall provide Business Associate with timely notice of the existence of such proceedings and such information, documents and other cooperation as reasonably necessary to assist Business Associate in establishing a defense to such action.

These indemnities shall survive termination of this Agreement, and Covered Entity reserves the right, at its option and expense, to participate in the defense of any suit or proceeding through counsel of its own choosing.

2. Mitigation. If Business Associate violates this Agreement or either of the HIPAA Rules, Business Associate agrees to mitigate any damage caused by such breach.
3. Rights of Proprietary Information. Covered Entity retains any and all rights to the proprietary information, confidential information, and PHI it releases to Business Associate.
4. Survival. The respective rights and obligations of Business Associate under Section E.3 of this Agreement shall survive the termination of this Agreement.
5. Notices. Any notices pertaining to this Agreement shall be given in writing and shall be deemed duly given when personally delivered to a Party or a Party's authorized representative as listed below or sent by means of a reputable overnight carrier, or sent by means of certified mail, return receipt requested, postage prepaid. A notice sent by certified mail shall be deemed given on the date of receipt or refusal of receipt. All notices shall be addressed to the appropriate Party as follows:

If to Covered Entity:

Attn: _____

If to Business Associate:

Attn: _____

6. Amendments. This Agreement may not be changed or modified in any manner except by an instrument in writing signed by a duly authorized officer of each of the Parties hereto. The Parties, however, agree to amend this Agreement from time to time as necessary, in order to allow Covered Entity's to comply with the requirements of the HIPAA Rules.
7. Choice of Law. This Agreement and the rights and the obligations of the Parties hereunder shall be governed by and construed under the laws of the State of Texas, without regard to applicable conflict of laws principles.
8. Assignment of Rights and Delegation of Duties. This Agreement is binding upon and inures to the benefit of the Parties hereto and their respective successors and permitted assigns. However, neither Party may assign any of its rights or delegate any of its obligations under this Agreement without the prior written consent of the other Party, which consent shall not be unreasonably withheld or delayed. Notwithstanding any provisions to the contrary, however, Covered Entity retains the right to assign or delegate any of its rights or obligations hereunder to any of its wholly owned subsidiaries, affiliates or successor companies. Assignments made in violation of this provision are null and void.
9. Nature of Agreement. Nothing in this Agreement shall be construed to create (i) a partnership, joint venture or other joint business relationship between the Parties or any of their affiliates, (ii) any fiduciary duty owed by one Party to another Party or any of its affiliates, or (iii) a relationship of employer and employee between the Parties.
10. No Waiver. Failure or delay on the part of either Party to exercise any right, power, privilege or remedy hereunder shall not constitute a waiver thereof. No provision of this Agreement may be waived by either Party except by a writing signed by an authorized representative of the Party making the waiver.
11. Equitable Relief. Any disclosure of misappropriation of PHI by Business Associate in violation of this Agreement will cause Covered Entity irreparable harm, the amount of which may be difficult to ascertain. Business Associate therefore agrees that Covered Entity shall have the right to apply to a court of competent jurisdiction for specific performance and/or an order restraining and enjoining Business Associate from any such further disclosure or breach, and for such other relief as Covered Entity shall deem appropriate. Such rights are in addition to any other remedies available to Covered Entity at law or in equity. Business Associate expressly waives the defense that a remedy in damages will be adequate, and further waives any requirement in an action for specific performance or injunction for the posting of a bond by Covered Entity.
12. Severability. The provisions of this Agreement shall be severable, and if any provision of this Agreement shall be held or declared to be illegal, invalid or

unenforceable, the remainder of this Agreement shall continue in full force and effect as though such illegal, invalid or unenforceable provision had not been contained herein.

13. **No Third Party Beneficiaries**. Nothing in this Agreement shall be considered or construed as conferring any right or benefit on a person not party to this Agreement nor imposing any obligations on either Party hereto to persons not a party to this Agreement.
14. **Headings**. The descriptive headings of the articles, sections, subsections, exhibits and schedules of this Agreement are inserted for convenience only, do not constitute a part of this Agreement and shall not affect in any way the meaning or interpretation of this Agreement.
15. **Entire Agreement**. This Agreement, together with all Exhibits, Riders and amendments, if applicable, which are fully completed and signed by authorized persons on behalf of both Parties from time to time while this Agreement is in effect, constitutes the entire Agreement between the Parties hereto with respect to the subject matter hereof and supersedes all previous written or oral understandings, agreements, negotiations, commitments, and any other writing and communication by or between the Parties with respect to the subject matter hereof. In the event of any inconsistencies between any provisions of this Agreement in any provisions of the Exhibits, Riders, or amendments, the provisions of this Agreement shall control.
16. **Interpretation**. Any ambiguity in this Agreement shall be resolved in favor of a meaning that permits Covered Entity to comply with the HIPAA Rules and any applicable state confidentiality laws. The provisions of this Agreement shall prevail over the provisions of any other agreement that exists between the Parties that may conflict with, or appear inconsistent with, any provision of this Agreement or the HIPAA Rules.
17. **Regulatory References**. A citation in this Agreement to the Code of Federal Regulations shall mean the cited section as that section may be amended from time to time.

Agreed to:

BUSINESS ASSOCIATE

By: _____
(Authorized Signature)

Name: _____
(Type or Print)

Title: _____

Date: _____

**THE UNIVERSITY OF TEXAS
HEALTH SCIENCE CENTER AT
SAN ANTONIO**

By: _____
(Authorized Signature)

Name: _____
(Type or Print)

Title: _____

Date: _____