REQUEST FOR PROPOSAL

by

The University of Texas Southwestern Medical Center

for

Selection of a Vendor to Provide

Consulting Services to assist in the regulatory ANDA filings to the US-FDA for the radiopharmaceuticals $^{18}$F-FDG Injection and $^{13}$N-NH$_3$ Injection.

RFP No. MD-020916

Submittal Deadline: 3:00 p.m. on Wednesday, February 24, 2016

Issued: February 9, 2016
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SECTION 1

INTRODUCTION

1.1 Description of the University

The University of Texas Southwestern Medical Center ranks among the world’s leading academic medical centers, patient-care providers, and research institutions. Its faculty members, who are responsible for a broad array of groundbreaking biomedical research and patient care advances, are respected for their dedication to teaching, research, and clinical care. UT Southwestern’s physicians and other health care practitioners (e.g., nurses, physician assistants, psychologists, therapists, etc.) provide patients with the highest-quality care throughout the Medical Center’s two University Hospitals, outpatient and ambulatory clinics, and affiliated hospitals.

Part of The University of Texas System, UT Southwestern includes three degree-granting institutions: UT Southwestern Medical School, UT Southwestern Graduate School of Biomedical Sciences, and UT Southwestern School of Health Professions. The schools and UT Southwestern faculty train more than 4,700 medical, graduate, and health professions students, residents, and postdoctoral fellows each year.

As one of the foremost research facilities in the world, UT Southwestern — with five Nobel Laureates and 21 members of the prestigious National Academy of Sciences — advances the frontiers of biomedical research and generates discoveries that benefit society. Ongoing support from federal agencies such as the National Institutes of Health, along with foundations, individuals, and corporations, provide more than $415 million per year to fund more than 3,300 research projects.

UT Southwestern provides inpatient care to nearly 92,000 patients and performs more than 2.1 million outpatient/ambulatory visits annually. Its hospitals (William P. Clements Jr. University Hospital and Zale Lipshy University Hospital) offer patients superior care and outstanding service provided by a highly trained staff. In addition, UT Southwestern operates seven clinic facilities on campus, three Clinical Centers located off-campus in the North Texas community, and offers extensive clinical services through a network of well-respected, affiliated hospitals.

In late 2015, UT Southwestern announced the creation of an integrated regional health network (Integrated Network) including UT Southwestern Medical Center and Texas Health Resources (Texas Health) systems. The Integrated Network is expected to improve the quality of care and enhance the efficiency and accessibility of providing health services to North Texans.

1.2 Background and Special Circumstances 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. In particular, Proposer should note that University is part of The University of Texas System (“UT System”), which is comprised of nine academic and six health universities described at http://www.utsystem.edu/institutions. UT System institutions routinely evaluate whether a contract resulting from a procurement conducted by one of
the institutions might be suitable for use by another, and if so, this could give rise to additional purchase volumes. As a result, in submitting its proposal in response to this RFP, Proposer should consider proposing pricing and other commercial terms that take into account such higher volumes and other expanded opportunities that could result from the eventual inclusion of other institutions in the purchase contemplated by this RFP.

1.3 **Objective of this Request for Proposal**

The University of Texas Southwestern Medical Center (the “University”) is soliciting proposals in response to this Request for Proposal to contract with one or more vendors/agencies to provide consulting services to assist in the regulatory ANDA filings to the US-FDA for the radiopharmaceuticals $^{18}$F-FDG Injection and $^{13}$N-NH$_3$ Injection. Responsibilities will include:

a. Complete and submit the labeler code request
b. Complete and submit the drug establishment registration, including the GDUFA self-identity
c. Review and edit the draft documents prepared by UT Southwestern for modules 1 and 3 of the ANDA $^{18}$F-FDG $^{13}$N-NH$_3$ and submissions
d. Finalize the above documents
e. Complete and draft ANDAs in eCTD format
f. Submit the final eCTD upon approval by UT Southwestern

Furthermore the chosen contractor will provide regulatory support by representing UT Southwestern as Regulatory agent and review FDA correspondence and information requests.
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 Standard Time on Wednesday, February 24, 2016 (the “Submittal Deadline”).

2.2 University Contact Person

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

Darr Oney
Assistant Director
UT Southwestern Medical Center
5323 Harry Hines Blvd
Dallas, Texas 75390-9056

Darr.Oney@utsouthwestern.edu

University specifically instructs all interested parties to restrict all contact and questions regarding this RFP to written communications (email is preferred, all email must reference the RFP #: MD-020916 in the subject line) forwarded to the University Contact. Multiple questions shall be submitted in a MS Word document. The University Contact must receive all questions or concerns no later than the close of business day on February 15, 2016. 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 the 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 the Contractor, will be those factors listed below:

2.3.1 the cost of goods and services;
2.3.2 the reputation of the Proposer and of the Proposer's goods or services;
2.3.3 the quality of the Proposer's goods or services;
2.3.4 the extent to which the goods or services meet the University's needs; 
2.3.5 the Proposer's past relationship with the University;
2.3.6 the impact on the ability of the University to comply with laws and rules relating to historically underutilized businesses and to the procurement of goods and services from persons with disabilities; 
2.3.7 the total long-term cost to the University of acquiring the Proposer's goods or services; and
2.3.8 any other relevant factor that a private business entity would consider in selecting a vendor.

2.4 Key Events Schedule

<table>
<thead>
<tr>
<th>Event</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Issuance of RFP</td>
<td>February 9, 2016</td>
</tr>
<tr>
<td>Deadline for Questions/Concerns</td>
<td>February 15, 2016</td>
</tr>
<tr>
<td>(ref. Section 2.2 of this RFP)</td>
<td></td>
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<tr>
<td>Submittal Deadline</td>
<td>February 24, 2016</td>
</tr>
<tr>
<td></td>
<td>3 p.m. Central Standard</td>
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<tr>
<td>(ref. Section 2.1 of this RFP)</td>
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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, the Contractor subcontracts any of the Services, then the Contractor must make a good faith effort to utilize HUBs certified by the Texas Building and Procurement Commission. 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 Chapter 1, *Texas Administrative Code*, Section 111.14, 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, included as a separate document, and incorporated for all purposes.

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

The Contractor will not be permitted to change its HSP unless: (1) the Contractor completes a newly modified version of the HSP in accordance with the terms of said HSP that sets forth all changes requested by the Contractor, (2) the 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 the Contractor to conform to the modified HSP.

2.5.4 Proposer must submit two (2) originals 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 two (2) originals 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 two originals 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.
SECTION 3

SUBMISSION OF PROPOSAL

3.1 Number of Copies

Proposer must submit a total of 3 complete and identical hard copies of its entire proposal and three (3) electronic copies on separate CD-ROMS or flash drives. 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. Proposers may request this document in an editable version to facilitate the completion of their response. A Word file will be provided.

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:

Physical Delivery Address:
Mr. Darr Oney
UT Southwestern Medical Center
4600 Harry Hines Boulevard – Third Floor
Dallas, TX 75235
214.648.6022

Fed-Ex or UPS Delivery Address:
Mr. Darr Oney
UT Southwestern Medical Center
5323 Harry Hines Boulevard – X3.500
Dallas, TX 75390-9056
214.648.6022

3.3 Proposal Validity Period

Each proposal must state that it will remain valid for University’s acceptance for a minimum of one hundred 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 Responses to questions and requests for information in the Specifications and Additional Questions Section (ref. Section 5 of this RFP)
3.5.5 Signed and Completed HUB Subcontracting Plan (HSP) (ref. Section 2.5), even if you do not plan to subcontract.
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, 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.”

4.2 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.

4.3 Eligibility Certification

Pursuant to Section 2155.004, Government Code, Contractor certifies that the individual or business entity named in this Agreement has not received compensation for participation in the preparation of the Request for Proposal related to this Agreement and 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.

4.4 Tax Certification

If Contractor is a taxable entity as defined by Chapter 171, Texas 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.

4.5 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.
4.6 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, the 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.

4.7 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 shall be in writing and shall be deemed to have been duly given or served when delivered by hand delivery or when deposited in the U.S. mail by registered or certified mail, return receipt requested, postage prepaid, and addressed as follows:

If to University: UT Southwestern Medical Center
5323 Harry Hines Blvd
Dallas, TX 75390-9226
Attention: Darr Oney
Fax: 214-648-6046
darr.oney@utsouthwestern.edu

with copy to: UT Southwestern Medical Center
5323 Harry Hines Blvd.
Dallas, TX 75390-9062
Attention: Shawn Cohenour
Fax: (214) 648-0845
Shawn.Cohenour@utsouthwestern.edu

If to Contractor: 
Street Address: 
Attention: 
Fax: 
Email:

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

4.8 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 without limitation providing all records requested. Contractor will include this provision in all contracts with permitted subcontractors.
4.9 Venue; Governing Law

Dallas 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.

4.10 Breach of Contract Claims

4.10.1 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:

4.10.1.1 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.

4.10.1.2 If the parties are unable to resolve their disputes under Section 4.11.1.1, 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.

4.10.1.3 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.
4.10.2 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.

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

4.11 Compliance with Law

Contractor is aware of, is fully informed about, and in full compliance with its obligations under existing applicable law and regulations, including but not limited to Title VI of the Civil Rights Act of 1964, as amended (42 USC 2000(D)), Executive Order 11246, as amended (41 CFR 60-1 and 60-2), Vietnam Era Veterans Readjustment Act of 1974, as amended (41 CFR 60-250), Rehabilitation Act of 1973, as amended (41 CFR 60-741), Age Discrimination Act of 1975 (42 USC 6101 et seq.), Non-segregated Facilities (41 CFR 60-1), Omnibus Budget Reconciliation Provision, Section 952, Fair Labor Standards Act of 1938, Sections 6, 7, and 12, as amended, Immigration Reform and Control Act of 1986, and Utilization of Small Business Concerns and Small Business Concerns Owned and Controlled by Socially and Economically Disadvantaged Individuals (PL 96-507), the Americans with Disabilities Act of 1990 (42 USC 12101 et seq.), the Civil Rights Act of 1991 and all laws and regulations and executive orders as are applicable.

4.12 University’s Right to Audit

At any time during the term of this Agreement and for a period of four (4) years thereafter University or a duly authorized audit representative of University, or the State of Texas, at its expense and at reasonable times, reserves the right to audit Contractor’s records and books relevant to all services provided under this Agreement. In the event such an audit by University reveals any errors/overpayments by University, Contractor shall refund University the full amount of such overpayments within thirty (30) days of such audit findings, or University, at its option, reserves the right to deduct such amounts owing University from any payments due Contractor.

4.13 Access to Documents

To the extent applicable to this Agreement, in accordance with Section 1861(v)(I)(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 agrees to allow, during and for a period of not less than four (4) years after the Agreement term, 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.
4.14 Insurance

4.14.1 Contractor, consistent with its status as an independent contractor, will carry at least the following insurance in the form, with the companies and in the amounts (unless otherwise specified) as University may require:

4.14.1.1 Workers' Compensation Insurance with statutory limits, and Employer’s Liability Insurance with limit of not less than One Million Dollars ($1,000,000) per accident or disease. Policies must include All States Endorsement and a waiver of all rights of subrogation and other rights against the University;

4.14.1.2 Commercial General Liability insurance, including Blanket Contractual Liability, Broad Form Property Damage, Personal and Advertising Injury, Completed Operations/Products Liability, Medical Expenses, Interest of Employees as additional insureds and Broad Form General Liability Endorsements, for at least One Million Dollars ($1,000,000) per occurrence on an occurrence basis;

4.14.1.3 Commercial Automobile Liability insurance covering all owned, non-owned or hired automobiles to be used by Contractor, with coverage for at least One Million Dollars ($1,000,000) Combined Single Limit Bodily Injury and Property Damage;

4.14.2 Contractor will deliver to University:

4.14.1.1 Evidence satisfactory to University in its sole discretion, evidencing the existence of all the insurance promptly after the execution and delivery hereof and prior to the performance or continued performance of any services to be performed by Contractor hereunder from or after the date of this Agreement; and

4.14.1.2 Additional evidence, satisfactory to University in its sole discretion, of the continued existence of all required insurance not less than thirty (30) days prior to the expiration of any required insurance. If, however, Contractor fails to pay any of the renewal premiums for the expiring policies, University will have the right to make the payments and set-off the amount thereof against the next payment coming due to Contractor under this Agreement.

Such insurance policies, with the exception of Workers' Compensation and Employer’s Liability, 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, giving University the right to pay the premium to maintain coverage, in which event Section 11.2.2 will apply.
4.14.3 The insurance policies required in this Agreement will be kept in force for the periods specified below:

4.14.3.1 Commercial General Liability Insurance, and

4.14.3.2 Workers’ Compensation Insurance and Employer’s Liability Insurance will be kept in force until the Services have been fully performed and accepted by University in writing.

4.15 Indemnification

4.15.1 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 (including reasonable attorneys’ fees), and other claims of any nature, kind, or description (collectively “Claims”) by any person or entity, arising out of, caused by, or resulting from Contractor’s performance under 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.

4.15.2 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.

4.16 Press Releases.

Except when defined as part of the Work, Contractor will not make any press releases, public statements, advertisement or other promotional materials using the name or logo of University or the name of any University employee, or referring to the Agreement or the engagement of Contractor as an independent contractor of University, or the purchase of goods or services by University, without the prior written approval of University. Requests for prior written approval of any such releases, public statements, advertisements or other promotional materials must be directed to University’s Vice President – Communications, Marketing and Public Affairs.
4.17 Assignment of Overcharge Claims

Contractor hereby assigns to University any and all claims for overcharges associated with the Contract arising under the antitrust laws of the United States, 15 U.S.C.A., Sec. 1 et seq., or arising under the antitrust laws of the State of Texas, Business and Commerce Code, Sec. 15.01, et seq.

4.18 Observance of University Rules and Regulations

Contractor agrees that at all times its employees, agents and permitted subcontractors (if any) will observe and comply with all regulations of the facilities, including but not limited to, no smoking, parking and security regulations.

4.19 Assignment and Subcontracting

Except as specifically provided in any Historically Underutilized Business Subcontracting Plan ("HSP") attached as Exhibit TWO to this Agreement and incorporated for all purposes, neither Contractor's interest in this Agreement, its duties and obligations under this Agreement nor fees due to Contractor under this Agreement may be subcontracted, assigned, delegated or otherwise transferred to a third party, in whole or in part, and any attempt to do so will (1) not be binding on University; and (2) be a breach of this Agreement for which Contractor will be subject to any remedial actions provided by Texas law, including Chapter 2161, Government Code, and 1 Texas Administrative Code ("TAC") Section 111.14. University may report nonperformance under this Agreement to the Texas Building and Procurement Commission ("TBPC") in accordance with 1 TAC Chapter 113, Subchapter F, Vendor Performance and Debarment Program. The benefits and burdens of this Agreement are, however, assignable by University.

4.20 Historically Underutilized Business Subcontracting Plan

If an HSP is attached to this Agreement, Contractor agrees to use good faith efforts to subcontract the Services in accordance with the HSP. 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 the TBPC. 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 TBPC in accordance with 1 TAC Chapter 113, Subchapter F, Vendor Performance and Debarment Program. University may also revoke this Agreement for breach and make a claim against the Contractor.

4.21 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.

4.22 Limitations

The parties to this Agreement are aware that there are constitutional and statutory limitations on
the authority of the University (a state agency) to enter into certain terms and conditions of this
Agreement, including, but not limited to, those terms and conditions relating to 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 shall not be binding on University except to the extent authorized by the laws and
Constitution of the State of Texas.

4.23 Affirmative Action

Contractor agrees that a written copy of Contractor’s Civil Rights "Affirmative Action Compliance
Program" will be provided simultaneously with this Agreement and incorporated for all purposes,
or if Contractor is not required to have such a written program, the reason Contractor is not
subject to such requirement will be provided in writing.

4.24 OSHA Compliance

Contractor represents and warrants that all articles and services furnished under this Agreement
meet or exceed the safety standards established and promulgated under the Federal
Occupational Safety and Health Law (Public Law 91-598) and its regulations in effect or
proposed as of the date of this Agreement.
4.25  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. Contractor agrees that a breach of this certification is a violation of the Equal Opportunity clause in this Agreement. The term "segregated facilities" means any waiting rooms, work area, rest rooms and wash rooms, entertainment areas, 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 such 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.

4.26  Premises Rules

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 permitted subcontractors (if any) to become aware of, fully informed about, and in full compliance with all applicable University rules and policies, including, without limitation, those relative to personal health, security, environmental quality, safety, fire prevention, noise, smoking, and access restrictions.

4.27  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 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 shall 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.

4.28 Office of Inspector General Certification

Contractor acknowledges that University is prohibited by federal regulations from allowing any employee, subcontractor, or agent of Contractor to work on site at University’s premises or facilities if that individual is not eligible to work on federal healthcare programs such as Medicare, Medicaid, or other similar federal programs. Therefore, Contractor shall not assign any employee, subcontractor or agent 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 shall perform an OIG sanctions check quarterly on each of its employees, subcontractors and agents during the time such employees, subcontractors and agents are assigned to work on site at University’s premises or facilities. Contractor acknowledges that University will require immediate removal of any employee, subcontractor or agent of Contractor assigned to work at University’s premises or facilities if such employee, subcontractor or agent 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://exclusions.oig.hhs.gov/

4.29 Access by Individuals with Disabilities

Contractor represents and warrants (the “EIR Accessibility Warranty”) that the electronic and information resources and all associated information, documentation, and support that it provides to University as a result of this Request for Proposal (collectively, the “EIRs”) comply with the applicable requirements set forth in 1 TAC Chapter 213 and 1 TAC Section 206.70 (as authorized by Subchapter M, Chapter 2054, Texas 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 fails or is unable to do so, then University may terminate any contract or agreement and Contractor will refund to University all amounts University has paid under such agreement within thirty (30) days after the termination date.
SECTION 5
SPECIFICATIONS AND ADDITIONAL QUESTIONS

5.1 General

UT Southwestern is seeking consulting services with one or more vendors/agencies to assist in the regulatory ANDA filings to the US-FDA for the radiopharmaceuticals $^{18}$F-FDG injection and $^{13}$N-NH$_3$ injection. The consultant should have expertise in US-FDA ANDA PET drug filings. This would include completing and submitting the labeler code request and drug establishment registration; reviewing, editing, and finalizing the draft documents prepared by UT Southwestern for modules 1 and 3 of the ANDA submissions; draft, complete, and submit ANDAs in eCTD format upon UT Southwestern approval.

In regards to the establishment registration and labeler code, the consultant will provide a list of information for compliance with FDA requirements, review and information provided by UT Southwestern for completeness. Once all documents are completed in accordance with FDA standards, the consultant will submit to FDA via Electronic Submissions Gateway (ESG). If any comments, questions or validation errors are received from FDA regarding the submission, the consultant will review and discuss with UT Southwestern and respond to the FDA accordingly.

ANDA submission services shall include review and regulatory support, and eCTD compilation and publishing support. The consultants shall have documented experience in specific guidance regarding the filing of the PET ANDAs. In particular, they will review draft documents prepared by UT Southwestern for Modules 1 and 3, will advise as to changes, revisions, and any additional information needed for the ANDAs; and will finalize documents containing any updated information received from UT Southwestern. The ANDA documents will be compiled and drafted in eCTD format for review and comments, then published and provided to UT Southwestern for review. The final eCTD will be published by the consultant and the ANDAs will be submitted to FDA via the Electronic Submissions Gateway (ESG) after approval by UT Southwestern.

5.2 Qualification Requirements (What your response should contain)

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

5.2.1. A brief synopsis of the Proposer’s related experience in conducting similar or related activities

5.2.2 Provide a list of relevant references, including organization name, contact information, size of the organization (e.g., identify organizational units or schools and number of employees) and a summary of services provided. The references must include a list of all organizations that the Contractor has worked with in the past two years to provide services similar to this project.

5.2.3. Identify the total number of billable Contractor hours to complete the engagement for these tasks

5.2.4. A description of the process Proposer will use to perform the Services
5.2.5. Please provide resumes of your proposed personnel to conduct the sessions and configuration and design efforts. Please note that UT Southwestern reserves the right to interview and accept or reject any proposed Contractor project member. UT Southwestern also reserves the right to request the removal of any Contractor project member at any point during the engagement.
SECTION 6
PRICING AND DELIVERY SCHEDULE

Proposal of: ____________________________
(Proposer Company Name)

To: The University of Texas Southwestern Medical Center

RFP No.: MD-020916

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

6.1 Pricing Per (Skill Set, Hour, etc.) Be specific in how you want your pricing to be reflected. You can provide a chart or spreadsheet.
6.2 University’s Payment Terms

University’s standard payment terms are “Net 30 days.” Indicate below the prompt payment discount that Proposer offers 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.

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

The 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 the 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 the Contractor.

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

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.
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 the 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, 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 claims, actions, suits, demands, costs (including, but not limited to reasonable attorneys' fees), damages, and liabilities, 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 and (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. 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 affirms that no compensation has been received for its participation in the preparation of the requirements or specifications for this RFP, in accordance with Section 2155.004, Government Code.

2.10 By signature hereon, Proposer certifies its compliance with all federal laws and regulations pertaining to Equal Employment Opportunities and Affirmative Action.

2.11 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.

2.12 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 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)

(main contact name and email address)

(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.