Request for Proposal

Proviso 33.36

Longitudinal, observational clinical research study assembling and analyzing highly complex, multi-dimensional molecular and clinical data, with a focus on high-risk diabetes patients in South Carolina.

Requirements for RFP

Spartanburg Regional Health Services District, Inc. ("SRHS") is requesting proposals from qualified vendors capable of executing a longitudinal, observational clinical research study targeting 1,000 patients in South Carolina at risk for developing chronic kidney disease (CKD). The study will require assembling and analyzing highly complex, multi-dimensional molecular and clinical data to look for patterns in genetic profiles to help identify patterns and pathways associated with disease progression to ultimately transform the therapeutic response. Pursuant to Proviso 33.36, as detailed in this Request for Proposal, requirements for submitting proposals are outlined in this document.

Please acknowledge your intent to reply by emailing: **lmckee@srhs.com**

Questions should be directed to the email address above. Contact with SRHS personnel regarding this project (other than the designated contact listed above) may disqualify your company.

RFPs should be submitted electronically to: **Chad McKee**. Due to security measures our inbound email is limited to 5MB. Proposals greater than 5MB should be submitted in zip file, thumb drive, or multiple emails.

Submission of Proposal shall constitute agreement to hold SRHS and its agents harmless for injuries and damages related to performance.

Late, incomplete, or unsigned proposals not conforming to the requirements of this RFP will not be considered. SRHS reserves the right to reject any and/or all proposals submitted as may be in the best interest of the institution.

The due date for responses to this RFP is **December 23, 2024**.

Submitted by:

Company Name:
Contact Name and Title:
Address:
Phone:
Email contact:
Contact Signature:
Date:

Instructions for Respondents

1. Pricing, amendments or withdrawal requests must be received prior to the proposal due date. It is the contractor's sole responsibility to ensure that these documents are received by SRHS prior to the response due date.
2. Submit your signed proposal along with the required forms. Please identify the RFP title on electronic submission. SRHS assumes no responsibility for unmarked or improperly marked electronic submissions. Unsigned offers will be rejected.
3. Contractors must clearly mark as "Confidential" each part of their bid which they consider to be proprietary information that could be exempt from disclosure under South Carlina Code Section 30-4-40 (the "South Carolina Freedom of Information Act"). The State of South Carolina reserves the right to determine whether this information should be exempt from disclosure and no legal action may be brought against SRHS or its agents for its determination in this regard.
4. By submission of an offer, you represent that all goods and services meet the requirements of the proposal during the contract period.
5. This Request for Proposal does not commit SRHS to award a contract, to pay any cost incurred in the preparation of the proposal response, or to procure or contract for goods or services listed herein.
6. Correction of errors in the request for proposal documents: No offer shall be altered or amended after specified time for opening.
7. SRHS intends to select a vendor on the basis of proposals received in response to this RFP and any other information it obtains from other sources regarding the vendor. SRHS may hold onsite vendor demos with selected finalists. SRHS reserves the right to make this final decision independent of any or all of the above factors.

General Provisions

1. SRHS reserves the right to reject any and all offers, to cancel a solicitation, and to waive any technicality if deemed to be in the best interest of SRHS.
2. Vendor/Respondent shall comply with applicable provisions of state and federal law regarding procurement and business relationships with government entities, including but not limited to South Carolina Code Section 8-13-700.
3. SRHS reserves the right to waive any provisions, general or special conditions, or specifications if deemed to be in the best interest of SRHS.
4. This solicitation is intended to promote competition. If any language, specifications, terms and conditions, or any combination thereof restricts or limits the requirements in this solicitation to a single source, it shall be the responsibility of the interested contractor to notify SRHS in writing within (5) days prior to the proposal due date. The Request for Proposal may or may not be changed but a review of such notification will be made prior to the award.

General Conditions

1. Default: in case of default by the contractor, SRHS reserves the right to purchase any or all items or services in default in the open market, charging the contractor with any excessive costs. Should such charge be assessed, no subsequent business will be considered nor purchase orders issued to the defaulting contractor until the assessed charge has been satisfied.

2. Non-Appropriation: Any contract entered into by SRHS resulting from this request for proposal shall be subject to cancellation without damages or further obligation when funds are not appropriated or otherwise made available to support continuation of performance in a subsequent fiscal period or appropriated year.
3. Publicity: Contractor agrees not to refer to award of this contract in commercial advertising in such a manner as to state or imply that the products or services provided are endorsed or preferred by the user. The contractor shall not include the SRHS name in a published list of customers without prior approval.
4. Compliance with State Law: Upon award of a contract under this proposal, the person, partnership, association or corporation to whom the award is made must comply with the laws of South Carolina which require such person or entity to be authorized and/or licensed to do business with this state. Notwithstanding the fact that application statutes may exempt or exclude the successful contractor from requirements that it be authorized and/or licensed to do business in this state, by submission of this signed response, the contractor agrees to subject himself to the jurisdiction and process of the courts of the state of South Carolina as to all matters and disputes arising or to arise under the contract and the performance thereof, including any questions as to the liability for taxes, licenses, or fees levied by the state.
5. Assignment: no contract or its provisions may be assigned, sublet, or transferred without the written consent of SRHS.
6. Compliance with Laws: the successful bidder will comply with all federal and South Carolina state laws, regulations, licensing and other requirements rationally related to or covering the scope hereof, including without limitation all such laws and regulations concerning fair employment and treatment of all employees, without regard or discrimination by reason of race, color, religion, sex, national origin or physical handicap.
7. Condition of Price: all costs and offers submitted shall remain effective for a minimum period of 90-days or until evaluation of bids is complete and award is made. Thereafter, the contract prices shall remain effective for the term of the contract.
8. Deviations from requirements: any deviation from requirements indicated herein must be clearly pointed out; otherwise, it will be considered that items offered are in strict compliance with these specifications, and successful contractor will be held responsible. Therefore, deviations must be explained in detail on separate attached sheet(s). The listing of deviations, if any, is required but will not be construed as waiving any requirements of the specifications. Deviations found in the evaluation of the bid and not listed may cause for rejection. Contactors offering substitute or equal items must provide information sufficient to determine acceptability of item offered.
9. Drug-Free workplace: by submittal of this bid, respondent certifies that respondent complies comply with South Carolina Code Section 44-107-30.
10. Bidder's Qualifications: Consideration will be given only to Respondents who provide conclusive evidence that the following requirements are met:
    a. Adequate capital and credit ratings sufficient to complete all operations under this contract in a satisfactory manner.
    b. An efficient workforce with satisfactory record and extensive knowledge to deliver the contemplated services.
    c. An adequate supply of applicable equipment in good operating condition to fulfill the contract.
11. Licenses, Permits, Insurance and Taxes: All costs for any required licenses, permits, insurance, and taxes shall be borne by the Contractor.

12. Insurance. The amount and types of insurance required should be reasonably commensurate with the hazards and magnitude of the undertaking, but in no event of lesser amount nor more restrictive than the limits of liability and schedule of hazards below described. Without limiting its liability under the contract agreement, the Provider shall procure and maintain, at its expense during the life of this contract, insurance of the types in the minimum amounts stated below:

Schedule	Limit
Workers Compensation As required by the state of South Carolina.	Statutory
Comprehensive General Liability Premises operations (single limit) Contractual liability Independent contractors Personal injury Products - completed operations	$1,000,000 per occurrence; $3,000,000 in the aggregate annually.
Automobile liability All owned, non-owned, and hired (combined)	$ 1,000,000
Excess/Umbrella liability Each occurrence	$ 1,000,000
Cyber-Liability	$_____

13. Subject to Contract: The implementation of any project awarded to Respondent shall be subject to terms and conditions set forth in a validly executed contract for services with SRHS. Such contract shall contain terms and conditions suitable to SRHS in its sole discretion.

I. Proposal Background

Scope of Service:

For several years the South Carolina State Budget has included provisions designed to enhance healthcare in rural South Carolina communities. The South Carolina General Assembly expressly recognized the potential for such, enacting the 2023-2024 Appropriations Act, which contains Budget Provisio 33.36, Biomedical Research Center, which requires South Carolina Department of Health and Human Services (SCDHHS) to contract with South Carolina public entities that include health service districts, health authorities, or agencies to develop a biomedical research center for the purpose of analyzing biological pathways, networks and molecular systems.

In 2024, Spartanburg Regional Health System (SRHS) requested funding from the State of South Carolina, through the Rural Health Initiative Proviso 33.36, to develop a virtual Biomedical Research Center for the evaluation of genetic profiles and patterns associated with disease risk to establish effective and therapeutic responses. The goal is to transform the orientation of healthcare from current disease treatment to one of wellness and prevention through the evaluation of gene and protein structures along with their functions, variations, interactions and other key discreet elements of the human condition. To accomplish this goal, SRHS proposed, and was awarded funding, to create a Biomedical Research Initiative for Scientific Knowledge ("BRISK") capable of accessing patients and assembling and analyzing highly complex, multi-dimensional molecular and clinical data that will focus on key chronic diseases plaguing South Carolina. BRISK provides a unique opportunity for South Carolina to create a biomedical research engine of the future.

To do this, BRISK will focus on adult-onset Type 2 Diabetes (T2D) that frequently transitions to chronic kidney disease (CKD). This progression requires expensive dialysis, causing a huge burden on the South Carolina Medicaid system and patient beneficiaries. Moreover, diabetes is mechanically and biologically related to other chronic diseases such as heart disease, kidney disease and cancer, such that any material finding relative to this initial patient population could have broader implications to benefit a much larger Medicaid population. It is from this patient population that evaluation of genetic profiles will help to identify patterns and pathways associated with disease progression to ultimately transform the therapeutic response.

II. Specifications and Requirements

Requirements for proposals are outlined below as three distinct stages:

In stage one, 1,000 patients with T2D and at high risk for developing CDK, will be identified to participate in a longitudinal, observational research study. This study cohort will be identified through electronic search of electronic health records (EHR) from multiple hospitals in the region. Once patients are enrolled in the study, they will be consented to provide blood samples, stool samples, urine samples and survey data up to three times in one year. Stage one relies on the consent and accrual of targeted patient population to collect a robust data set needed for stage two. Stage two will utilize the data collected in stage one to produce and analyze "human data clouds" for the study cohort, and host in a secure, deidentified, cloud-based database environment that

permits sophisticated integrated network analyses. The data clouds will include a multi-vector view of each individual participant including proteomics data (quantitative analysis of 3,000 individual proteins), genomics data (whole genome sequencing, deep immune profiling), metabolomics data (assessment of metabolites), stool microbiome (whole sequencing), wearable device or personally reported data (i.e. HR, PR, HRV, sleep, temperature, activity), survey data, and comprehensive clinical data from EHR.

In this stage, the data will be assembled, normalized, structured, and stored in a safe cloud-based environment so that it can be analyzed. A software platform will be developed to permit data fusion or integration, allowing for complex network analyses and system biology-based interfaces needed in stage three.

In stage three, personal data clouds will be populated with data fields from varying sources to enable a multi-vector view of each individual's relevant genetic and omics profile, as well as care history. Populated data clouds will be overlayed on top of the data assembled at the time of initial CKD detection and clinical diagnosis by standard criteria. Resulting data maps of individualized personal health clouds for the study group can be subjected to algorithms searching for data elements or combination of data elements with strong positive or negative correlation to dependent variable CKD disease diagnosis and/or progression.

Vender Selection Criteria include:

1. Ability to develop and structure an IRB clinical research protocol(s) and guidelines to meet the goals of the study and that reflect the clinical research guidelines to ensure appropriate procedures and ethical practices are maintained to protect the trial participants and data integrity
2. Have, or have the ability, to source an established, in good standing, medical data research institutional review board (IRB), to conduct data and human test studies
3. Established model for de-identification of patient data meeting HIPAA requirements and a proven IT infrastructure to gather and successfully incorporate and organize data, including a minimum of System and Organizational Controls 2 (SOC2) certification to manage information related risk
4. Significant experience in clinical research and diagnostic trials, clinical trials matching, consenting and enrolling patients in longitudinal studies
5. Established relationships with South Carolina hospitals and/or the ability to establish those relationships
6. Have experience working with genomics, proteomics, metabolomics, and microbiomics data for clinical research analysis
7. Experience building robust data sets and aggregating unique data elements into searchable formats
8. Ability to produce an annual standard report outlining costs, expenditures and associated metrics, as well as intermittent updates on cost allocation and project progress
9. Experience publishing clinical research studies in accredited journals
10. Can internally or externally provide the necessary resources or infrastructure to complete omics testing to include all sample collections
11. Ability to directly or indirectly produce analyses and clinical insights into all biologic and environmental factors

Preferred Criteria include:

1. IRB approved clinical research database warehouse
2. South Carolina based company

Respondents should provide background information regarding the following technical specifications:

1. Hardware and configuration specifications include a list of hardware, software, and configuration options
2. Data security and confidentiality programs, including but not limited to audit programs, access controls and HIPAA compliance
3. Please complete and review the attached security questionnaire
4. A copy of your annual report or audited financial statements for the past 2 years.
5. Describe any liens or lawsuits current, pending, or occurring in the past 3 years.
6. Describe any major reorganizations in your company in the past 3 years.
7. List the number of customers who have cancelled their contract with you or deinstalled your system or services.

Respondents should provide background information regarding Respondent's prior and current activities, including but not limited to:

1. Company history and core personnel
2. Prior experience in clinical research, clinical trials matching and enrolling patients in longitudinal studies
3. Prior experience working with genomics, proteomics, metabolomics, and microbiomics data for clinical research analysis and aggregating such data in searchable formats

Respondents should provide two active references of similar sized companies (at least one of which was implemented in the last 12 months); and two terminated references.

Active Reference Number 1 Company Name: Company Address: City, State, Zip Code: Telephone Number/E-Mail Address: Contact Person:	**Terminated Reference Number 1** Company Name: Company Address: City, State, Zip Code: Telephone Number/E-Mail Address: Contact Person:
Active Reference Number 2 Company Name: Company Address: City, State, Zip Code: Telephone Number/E-Mail Address: Contact Person:	**Terminated Reference Number 2** Company Name: Company Address: City, State, Zip Code: Telephone Number/E-Mail Address:

	Contact Person:

III. RFP Review Process

SRHS will evaluate each potential vendor based on the information provided in the RFP Response. The evaluation shall include, but is not limited to, the Respondent's experience, technology, communication capabilities, implementation and service; strength of references; and budget considerations. Additionally, SRHS shall consider the capability of the Vendor to fulfill the Contract; the time it will take the Vendor to complete the Contract; the past performance of a Vendor; the ability of the Vendor to meet Contract requirements; and any other unique factors documented that impact Vendor or product selection.

Responses will be evaluated based on the following criteria and scoring:

Rating Definition	Score
Exceeds all other vendors	4
Slightly higher than all other vendors	3
Equivalent to all other vendors	2
Slightly less than all other vendors	1
Does not meet criteria	0

Criteria	Weight (A)	Score (B)	A x B
Established model for de-identification of patient data meeting HIPAA requirements and a proven IT infrastructure to gather and successfully incorporate and organize data, including a minimum System and Organizational Controls 2 (SOC2) certification to manage information related risk	20%		
Significant experience in clinical research and diagnostic trials, clinical trials matching, consenting and enrolling patients in longitudinal studies	15%		
Ability to develop and structure IRB approved clinical research protocol(s) and guidelines to meet the goals of the study and that reflect the clinical research guidelines to ensure appropriate procedures and ethical practices are maintained to protect the trial participants and data integrity	10%		

Experience working with genomics, proteomics, metabolomics, and microbiomics data for clinical research analysis	10%		
Experience building robust data sets and aggregating unique data elements into searchable formats	10%		
Pricing model that shows your price points	10%		
Ability to internally or externally provide the necessary resources or infrastructure to complete omics testing to include all sample collections	5%		
Ability to produce quarterly standard reports outlining costs, expenditures and associated metrics, as well as intermittent updates on cost allocation and project progress	5%		
IRB approved data warehouse	5%		
Experience publishing clinical trial studies in accredited journals	5%		
South Carolina based company with established relationships with health systems in the region	5%		
Total	100%		

Certificate of Familiarity

The undersigned, having familiarized themselves with the information contained within this entire Request for Proposal and applicable amendments, submits the attached offer and other applicable information, which I verify to be true and correct to the best of my knowledge.

I certify that this offer is made without prior understanding, agreement, or connection with any corporation, firm or person submitting a proposal for the same materials, supplies or equipment, and is in all respects, fair and without collusion or fraud.

I agree to abide by all conditions of this proposal response and certify that I am authorized to sign this bid. I further certify that this bid is good for a period of ninety (90) days, unless otherwise stated.

Authorized Signature: _____

Please provide the following information:

Company Name as registered with IRS
Authorized Signatory Name
Authorized Signatory Title
Correspondence Address
Date
Email
Phone
Federal Tax ID Number
SC Sales and Use Tax Number