

COVID-19 Surveillance, Diagnostic Testing and Population Monitoring

Proposal and Project Agreement

FOR:

**The Board of County Commissioners of
Bourbon County Kansas**

1700 S. Main Street
Fort Scott, Kansas 66701

Attn: Jeffery Fischer

MRIGlobal Proposal No. 831798

April 20, 2020

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April 20, 2020

The Board of County Commissioners
of Bourbon County Kansas
1700 S. Main Street
Fort Scott, KS 66701

Attn: Jeff Fischer
Commissioner

Subject: MRIGlobal Proposal No. 831798, “COVID-19 Surveillance, Diagnostic Testing and Population Monitoring”

Dear Mr. Fischer:

MRIGlobal is pleased to submit Proposal No. 831798 for “COVID-19 Surveillance, Diagnostic Testing and Population Monitoring.” Set forth below are the: (1) Project Scope of Work; (2) Price, Invoices, and Payment; (3) Termination; (4) Project Management; (5) Acceptance; and (6) attached General Conditions.

1. Project Scope of Work

The Scope of Work is based on information provided by, and discussions with, The Board of County Commissioners of Bourbon County Kansas (“Client”), in conjunction with the expertise of MRIGlobal and their partner HeartToHeart Network LLC (“HToH”) and any applicable authoritative sources. A change to any Assumption, Protocol, Standard, and/or Deliverable listed below that impacts the Price and/or Project Duration may result in a Change Order.

1.1 Background and Overall Scope

MRIGlobal, with their partner HToH, have the capability, capacity and experience to provide COVID-19 surveillance and diagnostic testing for communities in need, including communities at the federal, regional, state, and local levels. MRIGlobal has established surveillance and diagnostic workflows, platforms, assays and reagents. MRIGlobal staff are trained to receive, test, and report results for molecular (RT-PCR) and serology (RDT and ELISA) tests. Capacity currently includes up to one-hundred (100) samples per day, with the ability to expand, through a written Change Order as described below) to four-hundred (400) samples per day from our Kansas City, MO and Gaithersburg, MD locations.

MRIGlobal will receive samples from Client’s designated representative(s), or an authorized third-party, upon advance written notification by Client of such authorized persons. Time from

sample receipt to result reporting is approximately six (6) hours. MRIGlobal’s partner, HToH, will provide an app based mobile phone software solution that can efficiently and remotely identify and manage populations impacted by COVID-19. The system offers the ability to trace contacts and support communications between clinicians and patients, providing an indicator of the spread and control of COVID-19. The system also recommends public health actions to individuals in accordance with the Center for Disease Control and Prevention (“CDC”) and physician guidance, including return to work/duty decision tools based on symptomatic diagnosis, and RT-PCR and/or serology based diagnostic testing.

1.2 Project Assumptions

- This work will be conducted at MRIGlobal’s Kansas City, MO headquarters facility and the HToH offices in Fairway, Kansas.
- MRIGlobal has already established a testing approach based on the Food and Drug Administration’s (“FDA”) approved Emergency Use Authorization (“EUA”) protocols for laboratory based work.
- MRIGlobal has all the necessary equipment to perform this work and will procure all reagents and consumables required to perform the RT-PCR.
- Serological testing with Rapid Diagnostic Test (“RDTs”) are assumed to be performed by Clinicians, not MRIGlobal. RDT Tests could be identified and/or purchased by MRIGlobal if requested. FDA EUA approved RDT tests are available.
- Serological testing with enzyme-linked immunosorbent assays (ELISA) will be performed by MRIGlobal upon Client approval. FDA EUA approved ELISA tests are not yet available.
- All sample collection will be managed by the Client.
- All sample collection materials will be procured by the Client.
- Changes to the approved Project Tasks will result on the need to renegotiate price.
- The scope of this effort is currently limited to a pilot study for one (1) year covering a population of less than 20,000.
- HToH shall retain all ownership and other proprietary rights to software developed under their scope of this work.

1.3 Project Task Descriptions

MRIGlobal and HToH will execute testing strategies described below.

1.3.1 Task 1: Establish Testing using RT-PCR based Protocols

1.3.1.1 Surveillance protocols

- Surveillance protocols based on the CDC’s guidance and assay protocols are currently available. MRIGlobal will establish capabilities and conduct up to five-hundred (500) RT-PCR tests per week, with same day turn-around time from its Kansas City, MO location.

1.3.1.2 Diagnostic EUA protocols

- Diagnostic EUA protocols will be conducted in MRIGlobal’s CLIA laboratories based on CDC guidance using commercially available EUA RT-PCR protocols. MRIGlobal will establish capabilities and conduct up to five-hundred (500) tests per week, with same day turn-around time from its Kansas City, MO location.

1.3.1.3 *Optional: Point-of-Care/Point-of-Need Diagnostic EUA protocols*

- Diagnostic EUA protocols can be conducted using appropriate and available Point-of-Care/Point-of-Need technologies and protocols (Mesa Biotech Accula Test; Abbott ID NOW Test; Cepheid Xpert Xpress; BioFire Film Array; BD Veritor System, etc.) in resourced constrained environments at the patient location with use of MRIGlobal’s Mercury Lab or with available, appropriate space within an office/clinic type facility. This testing is subject to the availability of reagents.
- If Client wishes to select this optional subtask, a Change Order will be required.

1.3.2 **Task 2: Establish Testing using Serology Protocols**

1.3.2.1 *Serology (IgM and IgG) RDT and ELISA Protocols*

- Serology (IgM and IgG) protocols that require intravenous blood draws or finger sticks are commercially available for surveillance and diagnostic use. Available tests include Rapid Diagnostic Tests (RDTs) and Enzyme-Linked Immunosorbent Assays (ELISAs). RDTs can be used in resource-limited settings at the patient location with use of MRIGlobal’s Mercury Lab and ELISA’s can be used for higher throughput applications in MRIGlobal laboratories. MRIGlobal will establish capabilities and conduct up to five-hundred (500) tests per week, with same day turn-around, time from its Kansas City, MO location. Medical professionals would need to conduct intravenous blood draws. This testing is subject to the availability of FDA EUA reagents.

1.3.3 **Task 3: Training on RT-PCR Surveillance and Diagnostic Protocols**

1.3.3.1 *Training at Bourbon County Kansas Identified Laboratory Facilities*

- If the Client, in cooperation with the Southeast Kansas Multi County Health Department, can identify laboratory facilities and staff, MRIGlobal will support the development of protocols and conduct on-site training of designated staff. The exact training will be dependent on the FDA EUA reagents and equipment that are available and can be procured by the Client. At the time of the writing of this proposal, the Cepheid Xpert Xpress SARS-CoV-2 EUA Protocol (<https://www.fda.gov/media/136314/download>) is assumed to be the protocol that will be trained. MRIGlobal will develop and provide a training plan and protocols, including a curriculum and training documentation. Training will conclude with a demonstration of capability for all trainees before they can operate independently. Training will include up to four (4) staff (trainees).

1.3.4 **Task 4: Establish Surveillance and Patient Management Monitoring System**

1.3.4.1 *Patient Management Monitoring System*

- In further support of the surveillance needs during the COVID-19 crisis, MRIGlobal, with their partner HToH, can offer a COVID-19 surveillance and patient management monitoring system. The system integrates physiological data, signs and symptoms submitted by people that enable proactive management of the spread of the COVID-19. The patient, system administrators and clinicians can receive actionable and meaningful information pertaining to diagnosis, care, quarantine and isolation. It supports containment of disease spread using advanced analytics, algorithms and develops guidelines for public health action, including return to work/duty decision tools. In addition, data can be linked to local, regional, or national COVID-19 patient population registries.

- The scope of the HToH Patient Management Monitoring System functionality includes:
 - Capturing symptoms, underlying conditions, location, and other information pertinent to public health via a mobile application or web browser link.
 - Identifying participants through this reporting as confirmed infected, suspected infected, and not yet infected (or possibly asymptomatic).
 - Longitudinally tracking the development of symptoms and the movement of the participant.
 - Prompting health authorities regarding those participants for whom testing is warranted.
 - Evaluating progression of the disease across the participating population.
 - Integrating diagnostic laboratory testing data.

1.3.4.2 Client Engagement

- HToH will supply the necessary functionality and tools for electronic reception of the participants' collected readings, and presentation of those data and trends to health authority coordinators. Engagement with the Client will include the following activities:
 - Develop solution and implementation parameters.
 - Establish the final version of the remote assessment.
 - Establish the necessary dashboards for managing the engagement.
 - Support the client in training of users and performs go live testing of software as implemented.
 - Roll out the application to self-identified participants.
 - Client users log in to system to review data acquired from participant users of the application.
 - Client engages population based on the results of the remote application and the dashboard.

1.3.4.3 Software as a Service (SaaS) and Technical Support

- Operation and Maintenance of HToH's technical platform.
- Includes hosting and license fees and update services associated with HToH's technical platform.
- Client project team will be trained to provide first-line support for use of the application by community members, and HToH will provide support to the Client's project team for issues associated with the technical platform for the duration of the project. These services will be provided by telephone and email on business days between the hours of 9:00 a.m. and 5:00 p.m. (Central Time).

1.3.4.4 Professional Services

- The professional service which includes technical configuration and customization required to deliver the existing, generally available, software. This includes:
 - Deployment analysis, system supported workflow analysis, project management, definition of evaluation criteria, and feedback sessions with the project team from project kickoff to release to end-users.

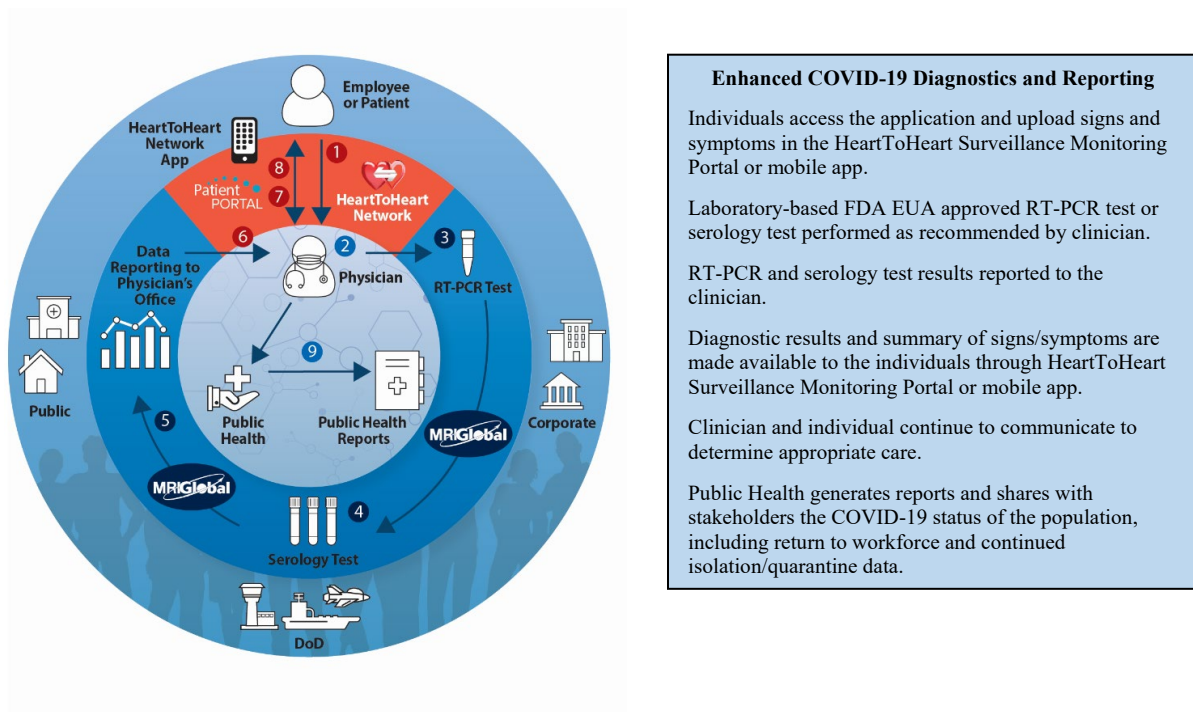
- Train-the-trainer support for MRIGlobal so that its project team can support its end-users and patients to use the service effectively.
- Configuration of the project dashboard.

1.3.5 Task 5 & 6: Project Task Integration, and Operational Testing and Reporting

1.3.5.1 Enhanced Diagnostic and Reporting Strategy Development

- MRIGlobal proposes to integrate the above mentioned surveillance and diagnostic testing approaches with the HToH monitoring system to provide an “Enhanced Diagnostic and Reporting Strategy.” **Testing and reporting will be operationally implemented in Task 6 following completion of Task 5.** The integration of symptomatic diagnosis by a physician with RT-PCR and IgG/IgM serology tests will inform decision making related to discontinuation of quarantine for persons with COVID-19 and an individual’s ability to return to work/duty. It also informs decisions related to the continued isolation for at risk populations. The following graphic demonstrates how the elements of this proposed solution are integrated.

MRIGlobal and HeartToHeart Network’s Enhanced COVID-19 Diagnostics and Reporting Strategy



1.4 Deliverables

MRIGlobal will provide the following Deliverables:

- For surveillance, diagnostic, and serological testing, MRIGlobal will provide an overview of the “Enhanced COVID-19 Diagnostic and Reporting Strategy,” as well as all underlying protocols developed and deployed to conduct the testing.
- MRIGlobal will conduct requested testing and results will be provided to the designated recipient (clinician’s office) by 5:00 pm on the same day as sample receipt assuming samples are received by 12:00 pm.

- For RT-PCR training on the Cepheid Xpert Xpress SARS-CoV-2 EUA Protocol, MRIGlobal will develop and provide a training plan and protocols, including curriculum. Training documentation forms for each trainee will be provided.
- MRIGlobal and HToH will deliver a flexible, portal-based website that allows Client’s access to, and use of the HToH Software as a Service (SaaS) for population monitoring and surveillance management, including technical support.
- MRIGlobal will provide monthly reports outlining activities from the previous month. These reports will be submitted five (5) business days after completion of the month.
- MRIGlobal and HToH will participate in weekly teleconferences throughout the contract period of performance to discuss activities and progress.

1.5 Project Duration

MRIGlobal will use commercially reasonable efforts to meet the estimated project schedule for completion of the work required to operationally implement the proposed testing and reporting strategy as set out in Table 1 below. The estimated project schedule is dependent on availability of: 1.) Reagents for RT-PCR and serology test, 2.) Facilities, reagents and equipment for the optional training task, and 3.) Access to and availability of clinicians and public health staff to support the project task integration. The proposed period of performance is twelve (12) months.

Table 1. Estimated Project Schedule

Task	Week 1	Week 2	Week 3	Week 4-52
1- Establish RT-PCR Protocols				
2- Establish Serology Protocols				
3- Training on RT-PCR Protocols				
4- Establish Patient Monitoring System				
5- Project Task Integration				
6- Operational Testing and Reporting				

1.6 Project Change Orders

Client and MRIGlobal shall negotiate in good faith and expeditiously for appropriate adjustments, as applicable, to the Price and/or Project Duration as a result of one of the following: (a) the occurrence of an unexpected problem outside of normal circumstances that impacts the Scope of Work; (b) an addition to or change in the Scope of Work requested by Client; or (c) a change to an Assumption, Protocol, or Standard that impacts the Scope of Work. Any change to the Scope of Work, or adjustment to the Price or Project Duration, shall be formalized in a fully executed Change Order. Client’s acceptance of the Change Order shall not be unreasonably withheld.

2. Price, Invoices, and Payment

MRIGlobal offers to perform COVID-19 Surveillance, Diagnostic Testing and Population Monitoring according to the Prices summarized in Table 2 below. Tasks 1 and 2 will be conducted at no cost to the Client, with the exception of the optional subtask, “Point-of-Care/Point-of-Need Diagnostic EUA protocols” that will be priced at the request of the Client and documented in a Change Order. Task 3, 4 and 5 are priced on a fixed price basis. Task 6 includes the testing of surveillance and diagnostic samples via RT-PCR and serology on a fixed price per sample basis including labor and expenses (inclusive of consumables, waste disposal,

vendor expenses, etc.). MRIGlobal reserves the right to run samples in a batch size minimum of ten (10) samples therefore potentially lengthening the time to results. MRIGlobal will submit invoice for Task 4 immediately after contract signing. MRIGlobal will submit invoices upon completion of Tasks 3 and 5. MRIGlobal will submit monthly invoices based on the number of samples tested in Task 6. Client agrees to pay the invoice within thirty (30) days of receipt.

Table 2. Price Summary

Tasks	Price
1- Establish RT-PCR Protocols	\$0
2- Establish Serology Protocols (ELISA Tests)	\$0
3- Training on RT-PCR Protocols-Fixed Price	\$29,990
4- Establish Patient Monitoring System- Fixed Price	\$17,869
5- Project Task Integration- Fixed Price	\$4,854
6- Operational Testing RT-PCR - Fixed Price per Sample	\$105
6- Operational Testing Serology (ELISA Test)- Fixed Price per Sample	\$91

3. Termination

Client may terminate the Work for any reason by giving MRIGlobal ten (10) days’ written notice, during which interval MRIGlobal will terminate the Work, and if authorized, prepare and submit a summary report of all Work conducted. In the event of termination prior to completion of the Project, MRIGlobal will invoice Client, and Client agrees to pay MRIGlobal, on a cost reimbursement basis for all labor and expenses incurred in the performance of Work prior to the effective date of termination and in connection with ending the Project.

4. Project Management

MRIGlobal’s Global Health Surveillance & Diagnostics Division (GHSD) will perform this Project. Karen Peltier, Program Manager will serve as the project manager and technical point of contact. She may be contacted at (816) 326-5276 or kpeltier@mriglobal.org. For contractual questions, contact Sam Clevenger, Associate Corporate Counsel at (816) 326-5171 or sclevenger@mriglobal.org.

5. Acceptance

This Project may be authorized by returning a signed copy of this Proposal to Mr. Clevenger at the above stated email address. Your signature below indicates acceptance of all terms and conditions contained in this Proposal, including the attached General Conditions. This Proposal is valid for thirty (30) days after issuance.

Sincerely,

MRIGLOBAL



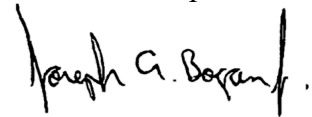
Karen Peltier
Program Manager

Approved for:

MRIGLOBAL



Sam Clevenger
Associate Corporate Counsel



Joseph A. Bogan, Jr., Ph.D.
Division Director, GHSD

Accepted by:

THE BOARD OF COUNTY COMMISSIONERS OF
BOURBON COUNTY KANSAS

By _____

Title _____

Date _____

GENERAL CONDITIONS

- 1. Defined Terms.** All capitalized terms not otherwise defined herein shall have the meaning ascribed to same in the Proposal.
- 2. Invoices / Payment Terms.** MRIGlobal will submit invoices to Client as set forth in the Proposal. Unless otherwise agreed to in the Proposal, Client agrees to pay all invoices within thirty (30) days of receipt. If payments are not timely, MRIGlobal may elect to impose a finance charge of 1.5% per month from the invoice due date until paid. Client agrees to reimburse MRIGlobal for its reasonable costs, including attorney's fees and expenses, incurred in collecting any past due amounts. Furthermore, MRIGlobal reserves the right to discontinue work if the Client fails to pay within the specified time.
- 3. Limited Warranty / Disclaimer.** MRIGlobal will perform the Work in a manner consistent with that degree of care, skill and diligence as is ordinarily exercised by professionals under similar conditions and circumstances, and its employees will possess the qualifications, licenses, skills and experience needed to perform such Work. MRIGlobal further warrants it will comply with all applicable laws, regulations, and industry standards in performance of the Work. EXCEPT TO THE EXTENT OF THE FOREGOING LIMITED WARRANTIES, MRIGLOBAL MAKES NO WARRANTY OR GUARANTEE, EXPRESS OR IMPLIED, WITH RESPECT TO THE WORK PERFORMED, INCLUDING, BUT NOT LIMITED TO, ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. Client acknowledges that MRIGlobal is only reporting data, results and conclusions generated by and pertaining to the Work performed. Any inference or decision of the Client based upon such data, results and conclusions shall be at the sole risk of the Client.
- 4. Limitation of Liability.** Due to the nature of the Work performed, no guarantee of results to be achieved is offered or intended. In the event of a material error in performance of the Work by MRIGlobal, Client's sole remedy shall be to have the defective performance promptly corrected at no additional expense to Client. In no event shall MRIGlobal's liability for defective performance exceed the amount paid by Client for Work performed under the Proposal. Neither party shall be liable to the other for lost profits or special, indirect, incidental, consequential or punitive damages of any kind.
- 5. Independent Contractor.** MRIGlobal's relationship to Client under the Proposal will be that of an independent contractor. Neither MRIGlobal nor its employees shall hold themselves out as employees of Client.
- 6. Force Majeure.** MRIGlobal shall not be liable for any failure to perform or delay in performance caused by any event beyond MRIGlobal's reasonable control, including but not limited to, acts of God, fire, explosion, weather, floods, disease, war, insurrection, civil strife, riots, terrorism, government action, or power failure, provided that such performance shall be excused only to the extent of and during such disability. Upon written notice to Client, any project-specific time point, deliverable, or deadline that is impacted by the *force majeure* event shall be automatically extended for a period of time equal to that of such disability. If any part of a Project is invalid as a result of such disability, MRIGlobal will, upon written request from the Client, but at the Client's sole cost and expense, repeat that part of a Project affected by the disability.
- 7. Publication.** Neither party will use the other party's name, symbol, trademark, trade name or logotype in connection with any publication or promotion without the other party's prior written consent. Project data, results, and reports shall be the property of Client and shall be used in any manner by Client in its sole discretion, provided that if Client intends to distribute any report generated by MRIGlobal outside Client's organization, the report shall be used in its entirety unless a summary or abridgement has been first approved in writing by MRIGlobal.
- 8. Confidential Information.** The obligations of the parties to protect from unauthorized disclosure any and all Confidential and Proprietary Information of the other party disclosed in relation to the Proposal shall be governed by the applicable Confidentiality and Nondisclosure Agreement entered into by the parties prior to the execution or performance of the Proposal.
- 9. Export Control.** Client and MRIGlobal agree that imports, exports, deemed exports and re-exports (including transfers of technology) related to the Work performed under the Proposal will be undertaken in compliance with applicable U.S. export control laws and regulations, or any foreign equivalents thereof. Both parties further agree to fully cooperate in complying with such laws and regulations and in assisting the other party with such compliance.
- 10. Indemnification.** The parties agree to indemnify, defend, and hold harmless the other party, and its affiliates, officers, directors, employees, agents, and insurers ("Indemnified Parties"), from any claim, lawsuit, loss, costs, damage or expense, including reasonable attorneys' fees, for bodily injury or death, or property damage ("Damage"), arising from or related to the Indemnifying Party's (a) negligent or intentional act or omission in the performance of any obligation under the Proposal, or (b) breach of any obligation, term or condition of the Proposal. Client further agrees to indemnify, defend and hold harmless MRIGlobal from any Damage arising from or related to the use by Client or any third-party of the results of the Work performed by MRIGlobal under the Proposal.
- 11. Applicable Law.** The parties agree that the Proposal and these General Conditions shall be governed by the laws of the State of Missouri.