STATE OF TENNESSEE
TENNESSEE DEPARTMENT OF HEALTH

REQUEST FOR INFORMATION
FOR
ELECTRONIC MANAGEMENT SYSTEM
FOR THE INSTITUTIONAL REVIEW BOARD

RFI # 34320-12117
JULY 8, 2016

1. STATEMENT OF PURPOSE:

The State of Tennessee, Department of Health (TDH) issues this Request for Information (RFI) for the purpose of procuring a software program to run the TDH Institutional Review Board (IRB). We appreciate your input and participation in this process.

2. BACKGROUND:

The TDH IRB is directed by a Federal Wide Assurance to ensure all guidelines are met and individuals’ health information is protected. TDH IRB meets this assurance by requiring an intuitive Electronic Management System (EMS) which is web-based, secure and will allow researchers from across the United States to access TDH IRB data. IRB human research studies continue to increase. Along with this demand comes the need for more services to allow the TDH IRB to keep pace with the needs of our human research customer(s). The new request system must meet the requirements specified in “Software Requirements Specification for TDH Data Request Tool, Version 1.2”.

Below is a list of features which are required in our TDH IRB EMS:

- Ability to access IRB(s) of other institutions.
- Web accessible via multiple internet browsers (ex: IE, FireFox, Chrome, etc.)
- Advanced search function (key words, project numbers, etc.).
- Agendas and minutes created and maintained in the system.
- Coordination of projects (TDH serves as IRB of record).
- Correspondence wizards.
- Create various reports for TDH executive staff.
- Cross institutional collaboration.
- Customer training on-line (ex: chat).
- Custom approval letter wizard.
- Dashboards (ex: researcher, committee).
- Data can be easily exported on a scheduled basis to an external TDH server for back-up.
- E-mail alerting capability.
• Electronic routing of projects for review.
• Electronic signature capabilities.
• Help desk and on-line support to TDH IRB staff and its customers.
• Host documents that are accessible to the researcher via download and upload.
• Interface with Collaborative Institutional Training Initiative (CITI) and allow CITI courses to be uploaded to projects.
• Instant access.
• Instant project approval notification.
• Library to hold TDH forms and IRB instructions for committee and researcher.
• Meeting scheduling function
• Multiple messaging alerts (ex: adverse reactions, protocol breach)
• Multiple levels of user access.
• Multiple site studies.
• Post notes and comments.
• Server and software hosted, updated and maintained by the company, i.e., cloud-based software.
• TDH must be able to fully control the content and placement of the documents. TDH should NOT rely on the company to make changes to document content.
• Tracking capabilities of current and historical studies.
• Versioning control
• Weekly project status reports (ex: Word, Excel, etc.)
• Regular system maintenance
• Transfer of historical and current information/data from the existing system to new system

3. COMMUNICATIONS:

3.1. Please submit your response to this RFI to:

Melissa Painter  
Tennessee Department of Health  
Service Procurement Program  
710 James Robertson Parkway, 5th Floor  
Andrew Johnson Tower  
Nashville, TN 37243  
Telephone: (615) 741-0285  
E-Mail: melissa.painter@tn.gov

3.2 Please feel free to contact the TDH with any questions regarding this RFI. The main point of contact will be:

Melissa Painter  
Tennessee Department of Health  
Service Procurement Program  
710 James Robertson Parkway, 5th Floor  
Andrew Johnson Tower  
Nashville, TN 37243  
Telephone: (615) 741-0285  
E-Mail: melissa.painter@tn.gov

3.3 Please reference RFI # 34320-12117 with all communications to this RFI.

3.4. A Pre-Response Tele-Conference will be held at the time and date detailed in the RFI § 4, Schedule of Events. This conference will be held to provide interested respondents with an overview of the State’s needs. This will also serve as an opportunity for respondents to
ask questions about the software to be procured. The conference telephone number is (888) 757-2790 and the participant passcode is 793536.

4. RFI SCHEDULE OF EVENTS:

<table>
<thead>
<tr>
<th>EVENT</th>
<th>TIME (Central Time Zone)</th>
<th>DATE (all dates are State business days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. RFI Issued</td>
<td></td>
<td>July 8, 2016</td>
</tr>
<tr>
<td>2. Pre-Response Teleconference</td>
<td></td>
<td>July 14, 2016</td>
</tr>
<tr>
<td>5. RFI Response Deadline</td>
<td></td>
<td>July 29, 2016</td>
</tr>
</tbody>
</table>

5. GENERAL INFORMATION:

5.1. Please note that responding to this RFI is not a prerequisite for responding to any future solicitations related to this project and a response to this RFI will not create any contract rights. Responses to this RFI will become property of the State.

5.2. The information gathered during this RFI is part of an ongoing procurement. In order to prevent an unfair advantage among potential respondents, the RFI responses will not be available until after the completion of evaluation of any responses, proposals, or bids resulting from a Request for Qualifications, Request for Proposals, Invitation to Bid or other procurement method. In the event that the state chooses not to go further in the procurement process and responses are never evaluated, the responses to the procurement including the responses to the RFI, will be considered confidential by the State.

5.3. The State will not pay for any costs associated with responding to this RFI.

6. INFORMATIONAL FORMS:

The State is requesting the following information from all interested parties. Please fill out the following forms:
<table>
<thead>
<tr>
<th>RFI #34320-12117</th>
</tr>
</thead>
<tbody>
<tr>
<td>TECHNICAL INFORMATIONAL FORM</td>
</tr>
<tr>
<td>1. RESPONDENT LEGAL ENTITY NAME:</td>
</tr>
<tr>
<td>2. RESPONDENT CONTACT PERSON:</td>
</tr>
<tr>
<td>Name, Title:</td>
</tr>
<tr>
<td>Address:</td>
</tr>
<tr>
<td>Phone Number:</td>
</tr>
<tr>
<td>Email:</td>
</tr>
<tr>
<td>3. BRIEF DESCRIPTION OF EXPERIENCE PROVIDING SIMILAR SCOPE OF SERVICES/PRODUCTS</td>
</tr>
<tr>
<td>4. BRIEF DESCRIPTION OF HOW OFTEN SOFTWARE IS UPGRADED AND THE PROCESS USED TO UPGRADE THE SOFTWARE.</td>
</tr>
<tr>
<td>5. WHAT FEEDBACK CAN YOU OFFER TDH IN REGARDS TO THE SOFTWARE REQUIREMENTS SPECIFICATION?</td>
</tr>
<tr>
<td>6. PLEASE DESCRIBE THE PRODUCT THAT YOU WOULD OFFER TDH TO MEET THE SOFTWARE REQUIREMENTS SPECIFICATION?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>COST INFORMATIONAL FORM</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Describe what pricing units you typically utilize for similar services or goods (e.g., per hour, each, etc.):</td>
</tr>
<tr>
<td>2. Describe the typical price range for similar services or goods</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ADDITIONAL CONSIDERATIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Please provide input on alternative approaches or additional things to consider that might benefit the State:</td>
</tr>
</tbody>
</table>