COUNTY OF SANTA CLARA, CALIFORNIA

REQUEST FOR PROPOSAL # 893
FOR

PERIOPERATIVE SERVICES TISSUE MANAGEMENT SYSTEM
DECEMBER 4, 2008

PROPOSALS DUE:
DECEMBER 24, 2008 by 3:00 P.M.

PROCUREMENT DEPARTMENT
2310 NORTH FIRST STREET, SUITE 201
SAN JOSE, CA 95131-1040

CONTACT: CHERYL LIU
408-491-7413
CHERYL.LIU@PROC.SCCGOV.ORG
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I. INTRODUCTION

A. INVITATION

The Santa Clara Valley Health and Hospital System (SCVHHS) Perioperative Services Department is seeking proposals from qualified firms to provide a hospital-wide biological tissue tracking system to document safe preservation, transportation, storage, handling and final disposition of allograft and autograft human tissue at Santa Clara Valley Medical Center. System should be expandable to include mechanical and other types of implants. The system should provide the following:

- Compliance with FDA (Food and Drug Administration) Federal Registry Title 21 regulations
- Compliance with TJC (The Joint Commission) Chapter 17 requirements
- Compliance with State CDPH (California Department of Public Health) Health and Safety Codes
- Compliance with AATB (American Association of Tissue Banks) National Standards
- Ability to create an outbound HL7 interface to the existing Perioperative surgical information system.

We are seeking proposals for an ASP solution. The proposal should include project management, implementation, training, and customizations, as well as ongoing maintenance and support.

Only proven system software products will be considered. The County is not interested in purchasing professional services to design and develop a system.

This RFP will result in a single source award.

B. BACKGROUND

1. Santa Clara Valley Health and Hospital System (SCVHHS):
   The County of Santa Clara operates Santa Clara Valley Health and Hospital System (SCVHHS) and Valley Health Plan (VHP). SCVHHS is comprised of an acute care public teaching hospital - Santa Clara Valley Medical Center (VMC) - as well as Ambulatory and Community Health Services (ACHS) outpatient
services, Custody, Public Health, Mental Health and Drug and Alcohol Services.

2. **Santa Clara Valley Medical Center (VMC)**

VMC is affiliated with Stanford University Medical School and provides a full range of inpatient, emergency, rehabilitation, neonatal, intensive care, high-risk maternity care, psychiatry, pediatric intensive care, and burn intensive care services. The Ambulatory outpatient services include both primary and specialty clinics located not only at VMC, but also at satellite facilities located throughout the County.

3. **Perioperative Services Department : Statistics**

<table>
<thead>
<tr>
<th>DESCRIPTION</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Operating Rooms</td>
<td>12</td>
</tr>
<tr>
<td>PACU / Secondary Recovery Beds</td>
<td>28</td>
</tr>
<tr>
<td>Number of Surgeries Scheduled Monthly</td>
<td>900</td>
</tr>
<tr>
<td>• Surgeons</td>
<td>88</td>
</tr>
<tr>
<td>• Anesthesiologists / CRNA</td>
<td>23</td>
</tr>
<tr>
<td>• Perioperative Nurses (RNs)</td>
<td>38</td>
</tr>
<tr>
<td>• Surgical Technicians</td>
<td>13</td>
</tr>
<tr>
<td>• Administrative Support Staff</td>
<td>20</td>
</tr>
</tbody>
</table>

4. **Information Services Department**

The Information Services Department is responsible for all systems and applications planning, development and support within the SCVHHS. Business units comprising I.S. are:

- New Systems Implementations
- Analysis and Support
- Technical Services (Network and Technology Operations)

Note: The software/hardware solution must work with state-mandated compliance and regulatory directives.
5. **Technical Environment**

**SANTA CLARA VALLEY HEALTH AND HOSPITAL SYSTEM**  
Information Services – Technical Services  

**Technical Standards – Intel Platform**

### SERVER

<table>
<thead>
<tr>
<th>Operating system</th>
<th>Windows Server 2003/Windows Active Directory</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hardware</td>
<td>Intel Dual Core 3.0 GHZ – 2MB cache, fiber/GBE NIC (redundant), SAN integration via Emulex 1000-L2 HBAs, dual processor, 2GB RAM per processor minimum, redundant power supplies. Blade technology preferred.</td>
</tr>
<tr>
<td>Backup</td>
<td>Veritas NetBackup 4.x and/or Tivoli Storage Manager (<em>enterprise backup</em>)</td>
</tr>
<tr>
<td>Server redundancy/cluster</td>
<td>Depends on application</td>
</tr>
<tr>
<td>Disk array</td>
<td>Raid 1(Blade), Standalone: RAID 1 (OS) RAID 5 (Data)</td>
</tr>
</tbody>
</table>

### DESKTOP/LAPTOP HARDWARE

| Mid-level PC with 17” monitor | HP DC7700 Convertible Mini-tower  
For most current spec see Valley Pages – Forms – Information Services – HHS Special Specifications |
| Small footprint PC with flat 17” LCD panel monitor (where space limitations require small footprint) | HP Ultra-Slim Desktop – DC7700  
For most current spec, see Valley Pages – Forms – Information Services – HHS Special Specifications |
| Monitor settings | 1024 x 768/ high color |
| Laptop | HP NC8430 – 15.4” display, Wi-Fi a/b/g  
For most current spec see Valley Pages – Forms – Information Services – HHS Special Specifications |
| Docking station | Basic docking station 1.1 |

### DESKTOP/LAPTOP SOFTWARE

<p>| Operating System | Windows XP with Service Pack 2 |
| Office applications | Microsoft Office 2003 Professional, SP2 |
| Email | Microsoft Outlook 2003 |
| Terminal emulation | NetManage Rumba 2000 v.6 |
| PDF reader | Adobe Acrobat Reader 7.0 |
| Desktop database | Microsoft Access 2003 |
| Internet browser | Microsoft Internet Explorer 6.0 |</p>
<table>
<thead>
<tr>
<th>Antivirus</th>
<th>Symantec AntiVirus Corporate Edition Version 10.x</th>
</tr>
</thead>
<tbody>
<tr>
<td>Java</td>
<td>Java Version 1.4.x</td>
</tr>
<tr>
<td>Encryption – Laptop Only</td>
<td>PointSec v6.1</td>
</tr>
</tbody>
</table>

**PRINTERS**

<table>
<thead>
<tr>
<th>Laser</th>
<th>HP LaserJet – Group - Mid-range printer is 4250TN</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>HP LaserJet – MFP is HP 4345TN</td>
</tr>
<tr>
<td></td>
<td>HP LaserJet – standalone is HP2105D</td>
</tr>
<tr>
<td>Impact</td>
<td>Not supported</td>
</tr>
<tr>
<td>Label</td>
<td>Zebra with network connectivity</td>
</tr>
<tr>
<td>Network interface</td>
<td>HP- Internal Jet Direct</td>
</tr>
</tbody>
</table>

*Technical Standards – Proprietary Platform (Midrange)*

**SERVER**

<table>
<thead>
<tr>
<th>Operating system</th>
<th>AIX, OS400, Sun Solaris</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hardware</td>
<td>64bit processor, connectivity to SAN a must, dual</td>
</tr>
<tr>
<td></td>
<td>NIC, redundant power supply. Manufacturer</td>
</tr>
<tr>
<td></td>
<td>configuration approval required.</td>
</tr>
<tr>
<td>Backup</td>
<td>Internal for OS, integration into enterprise backup</td>
</tr>
<tr>
<td></td>
<td>required. SCVHHS uses Veritas Netbackup 4.x and</td>
</tr>
<tr>
<td></td>
<td>Tivoli Storage Manager.</td>
</tr>
<tr>
<td>Server redundancy</td>
<td>Depends on application</td>
</tr>
<tr>
<td>Disk array</td>
<td>RAID 1 for server OS, RAID 5 for SAN allocation</td>
</tr>
</tbody>
</table>

**COMMUNICATION**

<table>
<thead>
<tr>
<th>Protocol</th>
<th>TCP/IP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Topology</td>
<td>Ethernet</td>
</tr>
<tr>
<td>Routers/ switches</td>
<td>Cisco</td>
</tr>
<tr>
<td>Bandwidth – network</td>
<td>Gigabit (sx/lx)</td>
</tr>
<tr>
<td>Bandwidth – to the desktop</td>
<td>10/100 MB/ second</td>
</tr>
<tr>
<td>Backbone</td>
<td>Fiber optic</td>
</tr>
<tr>
<td>Cable to the desktop</td>
<td>Category 5e UTP with RJ45 connections</td>
</tr>
</tbody>
</table>

**REMOTE AUTHENTICATION/SUPPORT**

| CRYPTOcard via Cisco VPN   |                                                 |

**UPS**

Must specify requirements from manufacturer. Computer room has UPS.
C. DEFINITION OF TERMINOLOGY

“Acronyms” used throughout this document include the following:

AATB – American Association of Tissue Banks
AORN – Association of periOperative Registered Nurses
CDPH – California Department of Public Health
FDA – Food and Drug Administration
HIPAA – Health Information Portability and Accountability Act
TJC – The Joint Commission
PM – Project Manager
SCVHHS – Santa Clara Valley Health and Hospital System
SCVMC – Santa Clara Valley Medical Center
VMC – Valley Medical Center

Definitions taken from the 2008 Perioperative Standards and Recommended Practices (AORN, Inc.):
Allografts – Grafts taken from a living or nonliving donor for transplantation to a different individual.

Autografts – Tissue derived from an individual for implantation exclusively on or in the same individual.

Tissue Bank – A facility that participates in procuring, processing, preserving, and/or storing human cells and tissue for transplantation.

Xenotransplant – Cells or tissue from a nonhuman animal source that are transplanted, implanted, or infused into a human.

Xenotransplantation – Any procedure that involves the transplantation, implantation, or infusion into a human recipient of either (a) live cells, tissues, or organs from a nonhuman animal source (eg, bovine heart valves); or (b) human body fluids, cells, tissues, or organs that have had ex vivo contact with live nonhuman animal cells, tissues or organs.

D. PROJECT SCOPE OF WORK

The SCVMC Perioperative Services Department is seeking a qualified vendor to provide a Tissue Management Tracking/Documentation System for biological implants to comply with our tissue license requirements that has the capability to record and track human tissue for implant from receipt to final disposition, including transport, storage, preparation, recall/suspected adverse event and identification of patient and personnel involved. The system should be
expandable to include mechanical and other types of implants and the potential for an HL7 interface to the existing surgical information system.

The selected vendor will work with the County to plan and implement a web-based tissue management tracking solution, including but not limited to an outbound HL7 interface to the existing surgical information system, training, disaster management and recovery, 24x7x365 ongoing maintenance and support, and version upgrades as necessary.

E. PROJECT MANAGEMENT

A Project Manager (PM) will be assigned by the vendor. The Project Manager will be responsible for all schedule related aspects of the project as well as be the primary point-of-contact with the County. The County will assign its own Project Manager who will interface with the vendor’s Project Manager.

At the start of the project, the vendor’s Project Manager will be responsible for developing a Project Plan to be approved by the County Project Manager prior to the start of work. The vendor’s Project Manager will also attend/phone conference for scheduled status meetings, presentations, and other meetings as designated by the County.

As necessary, the vendor’s Project Manager will be available onsite at County facilities in order to supervise vendor staff activities, coordinate tasks, identify and resolve problems and keep the County Project Manager informed of status and issues that require resolution.
II. CONDITIONS GOVERNING THE PROCUREMENT

This section of the RFP contains the anticipated schedule for the procurement and describes the procurement events as well as the conditions governing the procurement.

A. SEQUENCE OF EVENTS AND CONTACT INFORMATION

The Procurement Officer will make every effort to adhere to the following anticipated schedule:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Issue of RFP</td>
<td>12/4/2008</td>
</tr>
<tr>
<td>2. Deadline To Submit Written Questions</td>
<td>12/8/2008 by 5:00 p.m.</td>
</tr>
<tr>
<td>3. Response to Written Questions/RFP Amendments (Addendum)</td>
<td>12/11/2008 by 5:00 p.m.</td>
</tr>
<tr>
<td>4. Submission of Proposals</td>
<td>12/24/2008</td>
</tr>
</tbody>
</table>

PROCUREMENT OFFICER/POINT OF CONTACT:

The County has designated a Procurement Officer who is responsible for the conduct of this procurement whose name, address and telephone number are listed below:

Cheryl Liu, Procurement Manager
Procurement Department
County of Santa Clara
2310 N. First Street, Suite 201
San Jose, CA 95131-1040

Telephone: 408-491-7413
E-mail: Cheryl.Liu@proc.sccgov.org

All deliveries via express carrier should be addressed as follows:
Cheryl Liu, Procurement Manager – RFP # 893
Procurement Department
County of Santa Clara
2310 N. First Street, Suite 201
San Jose, CA 95131-1040

Any inquiries or request regarding this procurement should be submitted to the Procurement Officer in writing. Offerors may contact ONLY the Procurement Officer regarding this procurement. Other County employees do not have the authority to respond on behalf of the County.

B. EXPLANATION OF EVENTS

1. ISSUE OF RFP

This RFP is being issued by the County Procurement Department. Copies of this RFP including supporting documents may be obtained from RFP Depot’s web site at www.bidsync.com.

2. PRE-POPOSAL CONFERENCE

No Pre-Proposal Conference is scheduled for this RFP.

3. DEADLINE TO SUBMIT ADDITIONAL WRITTEN QUESTIONS

Potential Offerors may submit written questions as to the intent or clarity of this RFP until 5:00 P.M. PST as indicated in Paragraph II.A. The Procurement Officer will not respond to questions submitted in any other manner or format.

Additional written requests for clarification of distributed answers and/or addendums must be received by the Procurement Officer no later than three (3) days after the answers and/or addendums are posted on www.bidsync.com.

4. RESPONSE TO WRITTEN QUESTIONS/RFP AMENDMENTS

Written responses to written questions and any RFP amendments will be listed on an Addendum which will be posted on www.bidsync.com.
The County reserves the right to post addenda until the RFP closing date and time.

5. **SUBMISSION OF PROPOSAL**

PROPOSALS MUST BE RECEIVED NO LATER THAN 3:00 P.M. PACIFIC STANDARD TIME (PST) ON 12/24/2008. Proposals are to be received at the time and place listed below. All received proposals will be time stamped.

All deliveries via express carrier should be addressed as follows:

Cheryl Liu, Procurement Manager – RFP # 893
Procurement Department
County of Santa Clara
2310 N. First Street, Suite 201
San Jose, CA 95131-1040

Proposals must be sealed and labeled on the outside of the package to clearly indicate that they are in response to the RFP # and title as referenced on the cover page.

6. **INCURRING COST**

This RFP does not commit the County to award, nor does it commit the County to pay any cost incurred in the submission of the Proposal, or in making necessary studies or designs for the preparation thereof, nor procure or contract for services or supplies. Further, no reimbursable cost may be incurred in anticipation of a contract award.

CLAIMS AGAINST THE COUNTY: Neither your organization nor any of your representatives shall have any claims whatsoever against the County or any of its respective officials, agents, or employees arising out of or relating to this RFP or these procedures (other than those arising under a definitive Agreement with your organization in accordance with the terms thereof).
7. **GUARANTEE OF PROPOSAL**

Responses to this RFP, including proposal prices, will be considered firm and irrevocable for one-hundred and eighty (180) days after the due date for receipt of proposals or one-hundred eighty (180) days after receipt of a best and final offer, if one is submitted.

8. **BASIS FOR PROPOSAL**

Only information supplied by the County in writing or in this RFP should be used as the basis for the preparation of offeror proposals.

9. **FORM OF PROPOSALS**

No oral, telephone, facsimile or electronic proposals will be accepted.

10. **LATE RESPONSES**

All proposals submitted in response to this RFP must be delivered in person or received via courier or mail no later than the RFP due date and time. The Procurement Department time and date stamp will be the basis of determining receipt of proposal.

11. **NO PUBLIC PROPOSAL OPENING**

There will be no public opening for this RFP.

12. **CALIFORNIA PUBLIC RECORDS ACT (CPRA)**

All proposals become the property of the County, which is a public agency subject to the disclosure requirements of the Public Records Act (PRA, California Government Code section 6250 and following). If proprietary information is contained in or attached to the written proposal, and offeror claims that it falls within one or more PRA exemptions, the proposal must clearly identify the “proprietary” or “confidential” information. In the event of a PRA request for such information, the County will ask offeror to provide a legal basis for exempting it under the PRA. If the offeror provides an adequate legal basis to keep the information confidential, the County will request the
offeror agree in writing to defend and indemnify the County in any litigation that may result from denial of a PRA request. Unless offeror responds timely and agrees to do so, the County will disclose the information under the PRA.

13. **CONFIDENTIALITY**

All data and information gathered by the offeror and its agents in this RFP process, including reports, recommendations, specifications and data, shall be treated by the offeror and its agents as confidential. The offeror and its agents shall not disclose or communicate this information to a third party or use it in advertising, publicity, propaganda, or in another job or jobs, unless written consent is obtained from the County. Generally, each proposal and all documentation, including financial information, submitted by an offeror to the County is confidential until a contract is awarded, when such documents become public record under state and local law, unless exempted under CPRA.

14. **ELECTRONIC MAIL ADDRESS**

Most of the communication regarding this procurement will be conducted by electronic mail (e-mail). Potential offerors agree to provide the Procurement Officer with a valid e-mail address to receive this correspondence.

15. **USE OF ELECTRONIC VERSIONS OF THE RFP**

This RFP is being made available by electronic means. If accepted by such means, the offeror acknowledges and accepts full responsibility to insure that no changes are made to the RFP. In the event of conflict between a version of the RFP in the Offeror’s possession and the version maintained by the Procurement Department the version maintained by the Procurement Department must govern.

16. **COUNTY RIGHTS**

The County reserves the right to do the following at any time:

a. Reject any or all proposal(s), without indicating any reason for such rejection.
b. Waive or correct any minor or inadvertent defect, irregularity or technical error in a proposal or the RFP process, or as part of any subsequent contract negotiation.

c. Request that offerors supplement or modify all or certain aspects of their proposals or other documents or materials submitted.

d. Terminate the RFP, and at its option, issue a new RFP.

e. Procure any equipment or services specified in this RFP by other means.

f. Modify the selection process, the specifications or requirements for materials or services, or the contents or format of the proposals.

g. Extend a deadline specified in this RFP, including deadlines for accepting proposals.

h. Negotiate with any or none of the offerors.

i. Modify in the final agreement any terms and/or conditions described in this RFP.

j. Terminate failed negotiations with an offeror without liability, and negotiate with other offerors.

k. Disqualify any offeror on the basis of a real or apparent conflict of interest, or evidence of collusion that is disclosed by the proposal or other data available to the County.

l. Eliminate, reject or disqualify a proposal of any offeror who is not a responsible offeror or fails to submit a responsive offer as determined solely by the County.

m. To accept all or a portion of an offeror’s proposal.
III. RESPONSE FORMAT AND ORGANIZATION

A. NUMBER OF RESPONSES

Offerors shall submit only one proposal.

An Offeror may submit an amended proposal before the deadline for receipt of proposals. Such amended proposals must be complete replacements for a previously submitted proposal and must be clearly identified as such in the transmittal letter. The County personnel will not merge, collate, or assemble proposal materials.

Offerors will be allowed to withdraw their proposals at any time prior to the deadline for receipt of proposals. The offeror must submit a written withdrawal request signed by the offeror’s duly authorized representative addressed to the Director of Procurement.

B. NUMBER OF COPIES

Offerors must provide one (1) original and four (4) identical copies of their proposal to the location specified on or before the closing date and time for receipt of proposals. The original must be stamped “original” and contain original signatures on the necessary forms.

All of the original binders must be stamped “original”. Original Binder must contain all of the required signatures from the Offeror. The remaining sets should be copies of the originals.

Offerors must also provide two (2) electronic copies of their proposal in CD-ROM format, prepared using Microsoft Office 2003, Word, Excel and Project. The CD shall be included in the original Binder.

C. PROPOSAL FORMAT

All proposals shall be typewritten on standard 8 ½ x 11 paper (larger paper is permissible for charts, spreadsheets, etc.) and placed within a binder with tabs delineating each section. Hard copies should utilize both sides of the paper where practical.
1. **LETTER OF TRANSMITTAL**

Each proposal received must include a letter of transmittal. The letter of transmittal **MUST**:

a. Identify the submitting organization;

b. Identify the name, title, telephone and fax numbers, and e-mail address of the person authorized by the organization to contractually obligate the organization;

c. Identify the name, title, telephone and fax numbers, and e-mail address of the person authorized to negotiate the contract on behalf of the organization;

d. Identify the names, titles, telephone and fax numbers, and e-mail addresses of persons to be contacted for clarification;

e. Be signed by the person authorized to contractually obligate the organization

f. Acknowledge receipt of any and all addenda to this RFP; and identify all sections of the proposal that the Offeror claims contain “proprietary” or “confidential” information.

2. **PROPOSAL ORGANIZATION**

The proposal must be organized and indexed in the following format and must contain, at a minimum, all listed items in the sequence indicated:

Tab 1 - Letter of Transmittal
Tab 2 - Table of Contents
Tab 3 - Executive Summary
Tab 4 - Offeror Experience/Information
Tab 5 - Past Performance References
Tab 6 – Technical, Functional and Integration Narrative and Response Form (Appendix G)
Tab 7 - Implementation, Project Management, Training and Ongoing Support Documentation, Project Work Plan, Training Plan, System
3. **PROPOSAL PREPARATION INSTRUCTIONS**

Within each section of their proposal, Offerors should address the items in the order in which they appear in this RFP. All forms provided in the RFP shall be thoroughly completed and included in the appropriate section of the proposal.

The proposal summary may be included by Offerors to provide the Evaluation Committee with an overview of the technical and business features of the proposal; however, this material will not be used in the evaluation process unless specifically referenced from other portions of the Offeror’s proposal.
IV. REQUIREMENTS AND OFFEROR SUBMITTALS

This section contains requirements and relevant information Offerors should use for the preparation of their proposals. Offerors should thoroughly respond to each requirement.

A. OFFEROR’S CORPORATE INFORMATION

1. EXECUTIVE SUMMARY

Include an executive summary which should be a one or two page summary intended to provide the Evaluation Committee with an overview of the significant business features of the proposal.

2. OFFEROR EXPERIENCE/INFORMATION

The Offeror shall include in their proposal a statement of relevant experience. The Offeror should thoroughly describe, in the form of a narrative, its experience and success as well as the experience and success of subcontractors, if applicable in providing and/or supporting the proposed system.

In addition Offerors are required to provide the following information:

a. Offerors shall provide the company name, business address, including headquarters, all local offices, co-location locations (city/state), and telephone numbers.

b. Offerors shall provide the length of time they have been providing ASP services.

c. Offerors shall indicate any offices or facilities located within the County of Santa Clara that substantially and directly enhances the Offeror’s ability to perform the proposed contract.

d. Offerors shall provide a description of the offeror's organization, including names of principals, number of employees, client base, areas of specialization and expertise, and any other information that will assist the Evaluation Committee in formulating an opinion about the stability and strength of the organization.
e. Offerors shall provide the name of the jurisdiction in which the Offeror is organized and the date of such organization.

f. Offerors shall provide specifics on the number of certified local (stationed in greater Bay Area) technicians.

g. Offerors shall provide a description of the depth of their experience with installing and supporting the proposed system.

h. Offerors shall provide a discussion of the type and duration of the business relationship with the manufacturer(s) whose products are included in the proposed systems.

i. Offeror must identify the physical location of the application and data storage facilities.

j. Offeror shall describe the method used for change management and advance notification timeframe for application changes.

k. Offeror shall describe the data security guarantee (data encryption, data mining, and data mismanagement penalties (leakage, etc.).

l. Provide a complete disclosure if Offeror, its subsidiaries, parent, other corporate affiliates, or subcontractors have defaulted in its performance on a contract during the past five years which has led the other party to terminate the contract. If so, identify the parties involved and the circumstances of the default or termination.

m. A list of any lawsuits filed against the Offeror, its subsidiaries, parent, other corporate affiliates, or subcontractors in the past five years and the outcome of those lawsuits. Identify the parties involved and circumstances. Also, describe any civil or criminal litigation or investigation pending.

3. **FINANCIAL STABILITY/OFFEROR FINANCIAL INFORMATION**

   Offeror shall submit copies of the most recent years independently audited financial statements, as well as those for the preceding three years, if they exist. The submission shall include the audit opinion,
balance sheet, income statement, retained earnings, cash flows, and notes to the financial statements. If independently audited financial statements do not exist for the Offeror, the Offeror shall state the reason and, instead, submit sufficient information such as the latest Dun and Bradstreet report to enable the Evaluation Committee to determine the financial stability of the Offeror. The Procurement Officer may request and the Offeror shall supply any additional financial information requested in a timely manner.

4. **PAST PERFORMANCE (REFERENCES)**

The Offeror’s proposal shall include three different external references from clients who have completed their projects in the last three years, who are willing to validate the Offeror’s past performance on similar projects of size and scope. The minimum information that shall be provided for each client reference follows:

1. Name of the contact person;
2. Name of the company or governmental entity;
3. Address of the contact person;
4. Telephone number of contact person;
5. Email address of the contact person;
6. A description of the services provided and dates the services were provided;

B. **TECHNICAL, FUNCTIONAL AND INTEGRATION REQUIREMENTS**

The County is seeking a contractor to provide a complete solution to satisfy the functional and technical requirements and one who is capable of providing the stated capacity and service levels as well as the training and technical support required to maintain the system in an operational status. The technical, functional and integration requirements are to be defined referencing the technical, functional and integration requirements in Appendix G to the RFP.

Offerors must submit a thorough narrative supported by references to the technical documentation in response to questions asked in Appendix G. In addition, offerors must complete and submit with their proposals the Functional and Integration Requirements Response Form referenced in **Appendix G.**
C. **IMPLEMENTATION, PROJECT MANAGEMENT, TRAINING, AND ONGOING SUPPORT**

1. **Project Implementation Plan and Project Management Team**
   
a. Offeror shall include the implementation plan the Offeror intends to employ for the project and an explanation of how it will support the project requirements and logically lead to the required deliverables. The description shall include the organization of the project team, including accountability and lines of authority.

   b. Offerors shall describe services to be provided to ensure success of the project e.g. publicize the system to employees, organizing support infrastructure and processes, consulting on content set up and management etc.

   c. Offerors shall describe how the relationship between the County and Offeror will be managed from an account and technical support perspective.

   d. Offerors shall describe what is required of the County to ensure the successful implementation of the system.

   e. Offerors shall include the steps that will be undertaken to identify and resolve any issues or problems before, during and after the implementation.

   f. Offerors shall include a list of proposed project staff and key personnel.

   g. Offerors shall provide resumes, experience narratives and at least one reference for key personnel who will be assigned to the project, if awarded the contract.

   h. The experience narratives should include relationship with the Offeror, including job title and years of employment with the Offeror; role to be played in connection with the proposal; relevant certifications and experience.

   i. The references shall include the following information:
1. Name of the contact person;
2. Name of the company or governmental entity;
3. Address of the contact person;
4. Telephone number of contact person;
5. Email address of the contact person;
6. A description of the services provided and dates the services were provided.

2. **SOW - Training Plan**

   a. The Offeror’s proposal shall include a description for training three different audiences:
      1. Power users/administrators, general users, Content creators and Instructors.
      2. Technical administrators of the proposed system.
      3. Technical operations staff and support staff for the proposed system.

   b. Offerors must describe the type and quantity of training that will be provided for each audience. The description must include:
      1. The methods by which training will be provided e.g. online, on-site, webcast, self paced online courses etc;
      2. A recommended training curriculum;
      3. How the Offeror will work with the County to determine training needs and tailor the curriculum;
      4. What kind of training will be provided at what stage/phase of the project as well as follow-up training after implementation;
      5. Ability to provide training at a County location.

   c. Offerors’ descriptions must specify what training is included in the proposal and what is recommended beyond what is included.

   d. Offerors should describe the training facility requirements for physical layout, communication needs (internet connectivity, etc), projectors, # of computers, etc that are needed to fulfill the proposed training plan. Identify which elements of the training facility will by supplied by the Offeror.
e. The Offeror shall describe how system documentation is provided (online, hard copy etc) for the initial implementation as well as future updates and releases.

3. **SOW - Project Work Plan**

   The Offeror’s proposal shall include a detailed work plan for the implementation and operation of the proposed system.

   a. **Task Level** - The plan shall include all activities necessary for a successful project down to the task level. No task can exceed more than eighty hours in the work plan.

   b. **Identify All Resources** - The plan shall clearly identify all Offeror (including subcontractors) and using agency resources required to successfully complete the project. The Offeror shall provide job descriptions and the number of personnel to be assigned to tasks supporting implementation of the project. Identify County resources needed for each task.

   c. **Plan Progress Charts** - The plan shall include appropriate progress/Gantt charts that reflect the proposed schedule and all major milestones. A sample project plan shall be submitted using Microsoft Project.

4. **System Documentation**

   a. The Offeror shall describe the documentation provided to facilitate system implementation.

   b. The Offeror shall describe the System Administrator documentation provided.

   c. The Offeror shall describe if user groups exist to collaborate on issues pertaining to the Offeror’s software, including how often and where they meet. Explain if the user group is a separate independent organization or funded and organized by the Offeror.

   d. The Offeror shall attach a listing summarizing available stock (“canned”) reports provided by the solution and a sample of each.
e. The Offeror shall describe how system documentation is provided (online, hard copy etc) for the initial implementation as well as future updates and releases.

5. **Acceptance Test Plan**

The Offeror’s proposal shall include an acceptance test plan. The plan shall individually address each system component that comprises of the proposed system, approach for load testing, and number of people to be involved in testing. The plan should document the acceptance testing approach, resources and/or tools that may be used to validate the functions and features of the proposed system. Include an example test plan that is representative of the structure, content, and level of detail planned for this project.

6. **Risk Management**

Offerors shall submit with their proposals a risk assessment using the methodology published by the Project Management Institute or other comparable methodology. Offerors should include risk mitigation strategies as well as the resources the using agency may utilize to reduce risk.

7. **Value Added Services (Optional)**

Offerors are encouraged but not required to propose any optional value added services they believe would help the using agency to effectively implement, operate or use the proposed system. Information provided in this section must be directly relevant to emergency notification systems and not exceed two (2) pages in length.

8. **On-Going Service and Support**

a. Offerors must describe the post implementation follow-up activities that will be provided by the Offeror, specifically addressing the following tasks:
   1. Post-live system debugging to bring application into full conformance with documentation, proposal and modification specifications
2. Six-month and 12-month post live operational (non-technical) audits to review SCVMC utilization of the software and to provide recommendations for optimizing benefits.

3. Describe how application and support documentation is updated and distributed.

b. Provide the normal hours and describe the channels (phone, email, web, etc.) for support. Describe how after hours support is provided. Describe the support and escalation process, including response times.

c. Indicate the current version of the package. Indicate when the next major version of the package will be available. For major software upgrades, describe how often upgrades are released, how upgrades are defined, developed, tested and released, how customers are notified and educated about the upgrade. Describe the decision process on how new features and functions get included in the product.

d. Will software upgrades, or other maintenance window, impose a service disruption on the system? If so, discuss frequency and duration of the service disruptions.

e. Is there a user group? How often do they meet and where are the meetings? Is the user group a separate independent organization or funded and organized by the Offeror?

f. Offeror must submit a copy of the Offeror’s Service and Support Agreement.

9. **Security**

How will the security and confidentiality of the system data collected and entered into the system be maintained?

C. **COST PROPOSAL (APPENDIX B)**

Offerors shall complete the all pages of the Proposal Cost Response Form and submit it with their proposal. The proposed costs shall directly relate to the Project Work Plan.
The proposed cost shall include:
- All services required to fulfill the proposed project plan including licensing, labor, travel, and incidental costs.
- First year licensing / hosting cost
- Subsequent year licensing / hosting costs
- Itemized listing of optional cost elements
- Differentiation of costs by annual fee, one time, fixed fee, variable fee based on what factors, etc.
- Detailed description of licensing / hosting costs if not a fixed annual fee
- All taxes, licenses and other fees

D. OTHER SUBMITTALS

1. INSURANCE REQUIREMENTS (APPENDIX D)

Offerors shall provide a certificate(s) of insurance or a copy insurance declaration page(s) with their proposals as written evidence of their ability to meet the insurance certificate and other applicable County insurance requirements in accordance with the provisions listed in the RFP. In addition, Offerors shall provide a letter from an insurance agent or other appropriate insuring authority documenting their willingness and ability to endorse their insurance polities making the County an additional insured.

2. NON-COLLUSION DECLARATION (APPENDIX C)

Offerors shall complete and submit with their proposal the Non-Collusion Declaration with their proposals.

3. HIPAA (APPENDIX E)

Business Associates Agreement (HIPAA) - Offeror must complete and submit with proposal.

4. ASP SECURITY ASSESSMENT CHECKLIST (APPENDIX F)

ASP Security Assessment Checklist – Offeror must complete and submit with proposal.
5. **DECLARATION OF LOCAL BUSINESS (APPENDIX H)**

The Offeror has the option of completing the Declaration of Local Business and submitting with the proposal.

6. **RESPONSE TO AGENCY TERMS AND CONDITIONS (APPENDIX A)**

Should an Offeror object to any of the County’s terms and conditions, as contained in this appendix, the Offeror must propose specific alternative language and indicate the reason for the objection. The County may or may not accept the alternative language. General references to the Offeror’s terms and conditions or attempts at complete substitutions are not acceptable to the County. Offerors must provide a brief discussion of the purpose and impact, if any, of each proposed changed followed by the specific proposed alternate wording.

7. **OFFEROR’S ADDITIONAL TERMS AND CONDITIONS**

The Offeror must submit with their proposal any additional terms and conditions that they expect to have included in the contract negotiated with the County. Offerors must provide specific proposed wording and a brief discussion of the purpose and impact, if any.
V. EVALUATION

A. EVALUATION FACTORS

The Evaluation Criteria listed below will be utilized in the evaluation of the Offeror’s written proposals. The expectation is that those proposals in the competitive range may be considered for contract award. The proposal should give clear, concise information in sufficient detail to allow an evaluation based on the following criteria. An Offeror must be acceptable in all criteria for a contract to be awarded, to that Offeror whose proposal provides the best value to the County.

The proposal response shall enable the Evaluation Committee to evaluate the responsiveness and quality of the proposal to each of the RFP requirements/criteria listed in Section IV. Factors determining the best value include, but not limited to the following:

a. Adherence to the RFP;

b. Corporate strength, experience, financial strength, references and reputation of offeror;

c. Ability to meet the business and functional requirements, technical approach;

d. Methodology for implementation, project management and ongoing support;

e. Local Preference;

f. Cost.

LOCAL BUSINESS PREFERENCE:

In accordance with applicable sections of Board Policy, Section 5.3.13, in the formal solicitation of goods or services, the County of Santa Clara shall give responsive and responsible Local Businesses the preference described below.

“Local Business” means a lawful business with a physical address and meaningful “production capability” located within the boundary of the County of Santa Clara.
The term “production capability” means sales, marketing, manufacturing, servicing, or research and development capability that substantially and directly enhances the firm’s or bidder’s ability to perform the proposed contract. Post Office box numbers and/or residential addresses may not be used as the sole bases for establishing status as a “Local Business.”

In the procurement of goods or services in which best value is the determining basis for award of the contract, five percent (5%) of the total points awardable will be added to the Local Business score.

When a contract for goods or services, as defined in this policy, is presented to the Board of Supervisors for approval, the accompanying transmittal letter shall include a statement as to whether the proposed vendor is a Local Business, and whether the application of the local preference policy was a decisive factor in the award of the proposed contract.

This Local Business preference shall not apply to the following:
1. Public works contracts,
2. Where such a preference is precluded by local, state or federal law or regulation,
3. Contracts funded in whole or in part by a donation or gift to the County where the special conditions attached to the donation or gift prohibits or conflicts with this preference policy. The donation or gift must be approved or accepted by the Board of Supervisors in accordance with County policy, or
4. Contracts exempt from solicitation requirements under an emergency condition in accordance with board policy, state law and/or the County of Santa Clara Ordinance Code (Section A34-82).

In order to be considered for Local Preference, bidder must complete and submit Appendix H with proposal response.
APPENDIX A
SAMPLE
AGREEMENT BY AND BETWEEN
THE COUNTY OF SANTA CLARA AND “CONTRACTOR”

The County will post the Appendix A – Sample Agreement via an addendum to the RFP by December 11, 2008.
APPENDIX B
PROPOSAL COST RESPONSE FORM

Offeror’s Organization Name: _______________________________________________________

Section I – One Time Costs

<table>
<thead>
<tr>
<th>DESCRIPTION</th>
<th>PROPOSED PRICE</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Proposed Software (1st year license)</td>
<td></td>
</tr>
<tr>
<td>2. Customization</td>
<td></td>
</tr>
<tr>
<td>3. Installation/Implementation</td>
<td></td>
</tr>
<tr>
<td>4. Project Management</td>
<td></td>
</tr>
<tr>
<td>5. Training, including all materials</td>
<td></td>
</tr>
<tr>
<td>6. Travel Expenses* (see Section II below)</td>
<td>*</td>
</tr>
<tr>
<td>7. Other Costs** (see Section III below)</td>
<td>**</td>
</tr>
<tr>
<td>8. Applicable Sales Tax</td>
<td></td>
</tr>
<tr>
<td>Total One Time Cost</td>
<td></td>
</tr>
</tbody>
</table>

Section II – Travel Expenses*
Please itemize the travel expense in Row 6 in the above table, if any.

<table>
<thead>
<tr>
<th>Description</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td></td>
</tr>
</tbody>
</table>

*Tissue Management System RFP #893 31*
Section III – Other Costs**
*Please itemize all other costs, including, but not limited to: enhancement at an additional cost, proposed modules, third party software to operate the proposed software, etc. Use an attachment, if necessary. Be sure to state the total cost in Row 7 in the above table.

<table>
<thead>
<tr>
<th>Description</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>$</td>
</tr>
<tr>
<td>2.</td>
<td>$</td>
</tr>
<tr>
<td>3. **</td>
<td>$</td>
</tr>
</tbody>
</table>

Section IV – Recurring Annual Costs
List any recurring cost below.

<table>
<thead>
<tr>
<th>SOFTWARE, SERVICE AND SUPPORT</th>
<th>LIST PRICE/COST</th>
<th>PROPOSED COST</th>
<th>DISCOUNT % OFF LIST PRICE/COST</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Year One</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Year Two</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Year Three</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TOTAL</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Section V – Other Value Added Services:
Please itemize other value added services cost below.

<table>
<thead>
<tr>
<th>Description</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>$</td>
</tr>
<tr>
<td>2.</td>
<td>$</td>
</tr>
</tbody>
</table>

Offeror’s Name: ________________________________
APPENDIX C
NON-COLLUSION DECLARATION

I, _____________________________________________________________, am the
(Print Name)
________________________________________ of ________________________________,
(Position/Title) (Name of Company)

the party making the foregoing proposal that the proposal is not made in the interest of,
or on behalf of, any undisclosed person, partnership, company, association,
organization, or corporation; that the bid is genuine and not collusive or sham; that the
Offeror has not directly or indirectly induced or solicited any other Offeror to put in a
false or sham bid; and has not directly or indirectly colluded, conspired, connived, or
agreed with any Offeror or anyone else to put in a sham bid, or that anyone shall refrain
from bidding; that the Offeror has not in any manner directly or indirectly, sought by
agreement, communication, or conference with anyone to fix the bid price of the Offeror
or any other Offeror, or to fix any overhead, profit, or cost element of the bid price, or of
that of any other Offeror, or to secure any advantage against the public body awarding
the contract of anyone interested in the proposed contract; that all statements contained
in the bid are true; and, further, that the Offeror has not, directly or indirectly,
submitted his or her bid price or any breakdown thereof, or the contents thereof, or
divulged information or data relative thereto, or paid, and will not pay, any fee to any
corporation, partnership, company association, organization, bid depository, or to any
member or agent thereof to effectuate a collusive or sham bid.

I declare under penalty of perjury under the Laws of the State of California that the
foregoing is true and correct:

COMPANY NAME: ______________________________________________________

AUTHORIZED
SIGNATURE _____________________________________________________________

PRINT NAME: _____________________________________________________________

DATE: ________________________________________________________________
APPENDIX D
INDEMNITY AND INSURANCE REQUIREMENTS

Indemnity

The Offeror shall indemnify, defend, and hold harmless the County of Santa Clara (hereinafter "County"), its officers, agents and employees from any claim, liability, loss, injury or damage arising out of, or in connection with, performance of this Agreement by Offeror and/or its agents, employees or sub-offerors, excepting only loss, injury or damage caused by the sole negligence or willful misconduct of personnel employed by the County. It is the intent of the parties to this Agreement to provide the broadest possible coverage for the County. The Offeror shall reimburse the County for all costs, attorneys' fees, expenses and liabilities incurred with respect to any litigation in which the Offeror is obligated to indemnify, defend and hold harmless the County under this Agreement.

Insurance

Without limiting the Offeror's indemnification of the County, the Offeror shall provide and maintain at its own expense, during the term of this Agreement, or as may be further required herein, the following insurance coverage's and provisions:

A. Evidence of Coverage

Prior to commencement of this Agreement, the Offeror shall provide a Certificate of Insurance certifying that coverage as required herein has been obtained. Individual endorsements executed by the insurance carrier shall accompany the certificate. In addition, a certified copy of the policy or policies shall be provided by the Offeror upon request.

This verification of coverage shall be sent to the requesting County department, unless otherwise directed. The Offeror shall not receive a Notice to Proceed with the work under the Agreement until it has obtained all insurance required and such insurance has been approved by the County. This approval of insurance shall neither relieve nor decrease the liability of the Offeror.

B. Qualifying Insurers

All coverage’s, except surety, shall be issued by companies which hold a current policy holder's alphabetic and financial size category rating of not less than A- V, according to
the current Best’s Key Rating Guide or a company of equal financial stability that is approved by the County’s Insurance Manager.

C. Notice of Cancellation

All coverage as required herein shall not be canceled or changed so as to no longer meet the specified County insurance requirements without 30 days’ prior written notice of such cancellation or change being delivered to the County of Santa Clara or their designated agent.

D. Insurance Required

1. Commercial General Liability Insurance - for bodily injury (including death) and property damage which provides limits as follows:

   a. Each occurrence- $1,000,000

   b. General aggregate - $2,000,000

   c. Personal Injury - $1,000,000

2. General liability coverage shall include:

   a. Premises and Operations

   b. Personal Injury Liability

   c. Severability of interest

3. General liability coverage shall include the following endorsement, a copy of which shall be provided to the County:

   Additional Insured Endorsement, which shall read:

   “County of Santa Clara, and members of the Board of Supervisors of the County of Santa Clara, and the officers, agents, and employees of the County of Santa Clara, individually and collectively, as additional insured’s.”
Insurance afforded by the additional insured endorsement shall apply as primary insurance, and other insurance maintained by the County of Santa Clara, its officers, agents, and employees shall be excess only and not contributing with insurance provided under this policy. Public Entities may also be added to the additional insured endorsement as applicable and the offeror shall be notified by the contracting department of these requirements.

4. **Automobile Liability Insurance**

For bodily injury (including death) and property damage which provides total limits of not less than one million dollars ($1,000,000) combined single limit per occurrence applicable to all owned, non-owned and hired vehicles.

4a. **Aircraft/Watercraft Liability Insurance** (Required if Offeror or any of its agents or subofferors will operate aircraft or watercraft in the scope of the Agreement)

For bodily injury (including death) and property damage which provides total limits of not less than one million dollars ($1,000,000) combined single limit per occurrence applicable to all owned, non-owned and hired aircraft/watercraft.

5. **Workers’ Compensation and Employer's Liability Insurance**

a. Statutory California Workers' Compensation coverage including broad form all-states coverage.

b. Employer’s Liability coverage for not less than one million dollars ($1,000,000) per occurrence.

6. **Professional Liability / Errors and Omissions Insurance**

a. Coverage shall be in the amount of not less than one million dollars ($1,000,000) per occurrence/aggregate.

b. If coverage contains a deductible or self retention, it shall not be greater than fifty thousand dollars ($50,000) per occurrence/event.

c. Coverage as required herein shall be maintained for a minimum of two years following termination or completion of this agreement.
E. Special Provisions

The following provisions shall apply to this Agreement:

1. The foregoing requirements as to the types and limits of insurance coverage to be maintained by the Offeror and any approval of said insurance by the County or its insurance consultant(s) are not intended to and shall not in any manner limit or qualify the liabilities and obligations otherwise assumed by the Offeror pursuant to this Agreement, including but not limited to the provisions concerning indemnification.

2. The County acknowledges that some insurance requirements contained in this Agreement may be fulfilled by self-insurance on the part of the Offeror. However, this shall not in any way limit liabilities assumed by the Offeror under this Agreement. Any self-insurance shall be approved in writing by the County upon satisfactory evidence of financial capacity. Offeror’s obligation hereunder may be satisfied in whole or in part by adequately funded self-insurance programs or self-insurance retentions.

3. Should any of the work under this Agreement be sublet, the Offeror shall require each of its sub-offerors of any tier to carry the aforementioned coverage’s, or Offeror may insure sub-offerors under its own policies.

The County reserves the right to withhold payments to the Offeror in the event of material noncompliance with the insurance requirements outlined above.

F. Fidelity Bonds (Required only if offeror will be receiving advanced funds or payments)

Before receiving compensation under this Agreement, Offeror will furnish County with evidence that all officials, employees, and agents handling or having access to funds received or disbursed under this Agreement, or authorized to sign or countersign checks, are covered by a BLANKET FIDELITY BOND in an amount of AT LEAST fifteen percent (15%) of the maximum financial obligation of the County cited herein. If such bond is canceled or reduced, Offeror will notify County immediately, and County may withhold further payment to Offeror until proper coverage has been obtained. Failure to give such notice may be cause for termination of this Agreement, at the option of County.
APPENDIX E
BUSINESS ASSOCIATE AGREEMENT (HIPAA)
HIPAA - BUSINESS ASSOCIATE AGREEMENT PURSUANT TO THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996

I. Definitions

Terms used, but not otherwise defined, and terms with initial capital letters in this provision of the Agreement have the same meaning as defined under the Health Insurance Portability and Accountability Act of 1996, 42 USC §§ 1320d et seq. (“HIPAA”) and the implementing regulations. To the extent the HIPAA Privacy Rule changes the meaning of the terms; this provision shall be modified automatically to correspond to the meaning given in the rule.

“PROTECTED HEALTH INFORMATION,” as defined at 45 C.F.R. §§ 164.501, and 160.103, means information that:

(1) is created or received by a health care provider, health plan, employer or health care clearing house; and

(2) relates to the past, present of future physical or mental health or condition of an individual; the provision of health care to an individual or the past, present or future payment for the provision of health care to an individual, and (a) identifies the individual or (b) with respect to which there is a reasonable basis to believe the information can be used to identify the individual.

“ELECTRONIC PROTECTED HEALTH INFORMATION (E PHI)” as defined at 45 C.F.R. § 160.103(2), means Protected Health Information that is created electronically, transmitted electronically by electronic media, or is maintained in electronic media.

“BUSINESS ASSOCIATE” refers to __________________________ (Name of Contractor) in this Agreement.

“COVERED ENTITY” refers to the COUNTY of Santa Clara in this Agreement.

II. Duties & Responsibilities of BUSINESS ASSOCIATE

A. BUSINESS ASSOCIATE’S use and/or disclosure of PROTECTED HEALTH INFORMATION (“PHI”) will be limited to those permitted or required by the
terms of this Agreement or as REQUIRED BY LAW as defined pursuant to 45 CFR 164.501.

B. Unless otherwise limited by this Agreement, BUSINESS ASSOCIATE may use the PHI in its possession for the proper management and administration of the BUSINESS ASSOCIATE or to carry out its legal responsibilities.

C. BUSINESS ASSOCIATE may further disclose PHI for the proper management and administration of the BUSINESS ASSOCIATE or to carry out its legal responsibilities if the disclosure is required by law, or the BUSINESS ASSOCIATE receives reasonable assurances from the person receiving the PHI that it will be held confidentially, and will be used or further disclosed only as required by law and that the person receiving the PHI will notify the BUSINESS ASSOCIATE of any instances known in which the confidentiality has been breached.

D. BUSINESS ASSOCIATE must not use or disclose PHI in any manner that would constitute a violation of the PRIVACY RULE (Standard for Privacy of Individually Identifiable Health Information at 45 CFR part 160 and part 164, subpart A and E).

E. BUSINESS ASSOCIATE must use appropriate safeguards to prevent uses or disclosures of PHI other than as provided for by this Agreement.

F. BUSINESS ASSOCIATE must report in writing any use or disclosure of PHI not provided for by this Agreement to the COVERED ENTITY as soon as it learns of it.

G. BUSINESS ASSOCIATE must ensure subcontractors and agents that have access to, or to whom the BUSINESS ASSOCIATE provides PHI, agree in writing to the restrictions and conditions concerning the use and disclosure of PHI which are contained in this Agreement.

H. At the request of the COVERED ENTITY, BUSINESS ASSOCIATE must comply with the COVERED ENTITY’S request to accommodate an individual’s access to his/her PHI in a designated record set maintained by the BUSINESS ASSOCIATE. In the event an individual contacts BUSINESS ASSOCIATE directly about access to PHI, BUSINESS ASSOCIATE will not provide access to the individual but will forward the request to the COVERED ENTITY within three business days of contact.
I. Within fifteen business days of a request by the COVERED ENTITY, BUSINESS ASSOCIATE will comply with the COVERED ENTITY’S request to amend an individual’s PHI in a designated record set maintained by the BUSINESS ASSOCIATE. BUSINESS ASSOCIATE will promptly incorporate any such amendment into the PHI. In the event an individual contacts BUSINESS ASSOCIATE directly about making amendments to PHI, BUSINESS ASSOCIATE will not make any amendments to the individual’s PHI but will forward the request to COVERED ENTITY within three business days of such contact.

J. BUSINESS ASSOCIATE must keep a record of disclosures of PHI for a minimum of six years and agrees to make information regarding disclosures of PHI available to the COVERED ENTITY within fifteen days of a request by the COVERED ENTITY. BUSINESS ASSOCIATE must provide, at a minimum, the following information:

(1) the name of the individual whose PHI was disclosed.

(2) the date of disclosure;

(3) the name of the entity or person who received the PHI, and the address of such entity or person, if known;

(4) a brief description of the PHI disclosed; and

(5) a brief statement regarding the purpose and explanation of the basis of such disclosure.

BUSINESS ASSOCIATE is not required to maintain a record of disclosures of PHI under the following circumstances:

(1) To carry out treatment, payment or COUNTY health care operations, or activities that are incident to such disclosures;

(2) To individuals of their own PHI;

(3) Pursuant to a written authorization;

(4) For the facility’s directory or to person involved in the individual’s care or other notification purposes in 45 CFR 164.510;
(5) For national security or intelligence purposes;

(6) To correctional institutions or law enforcement officials;

(7) As part of a limited data set in accordance with 45 CFR 164.514(e); or

(8) That occurred prior to the compliance date for the covered entity.

K. BUSINESS ASSOCIATE must comply with any other restrictions on the use or
disclosure of PHI that the COVERED ENTITY may from time to time request.

L. BUSINESS ASSOCIATE must make its internal practices, books and records
relating to uses and disclosures of PHI available to the Secretary of the U.S.
Department of Health and Human Services or designee, for purposes of
determining the COVERED ENTITY’S compliance with the PRIVACY RULE.
BUSINESS ASSOCIATE must notify the COVERED ENTITY regarding any
information that BUSINESS ASSOCIATE provides to the Secretary concerning
the PHI. Concurrently with providing the information to the Secretary and upon
the COVERED ENTITY’S request, BUSINESS ASSOCIATE must provide
COVERED ENTITY with a duplicate copy of the information.

M. Upon the termination of this Agreement for any reason, BUSINESS ASSOCIATE
must return or destroy all PHI, including all PHI that is in the possession of
subcontractors or agents of the BUSINESS ASSOCIATE. BUSINESS ASSOCIATE
must not retain any copies of PHI. If return or destruction is not feasible,
BUSINESS ASSOCIATE must notify the COVERED ENTITY of the condition that
makes the return or destruction of PHI not feasible. If the COVERED ENTITY
agrees that the return or destruction is PHI is not feasible, BUSINESS
ASSOCIATE may dispose of the PHI, subject to all of the protections of this
Agreement and must make no further use or disclosure of the PHI.

N. The respective rights and responsibilities of BUSINESS ASSOCIATE related to
the handling of PHI survive termination of this Agreement.

O. Notwithstanding any other provision of this Agreement, the COVERED ENTITY
may immediately terminate this Agreement if BUSINESS ASSOCIATE has
materially violated its responsibilities regarding PHI under this Agreement upon
written notice.
P. **EPHI:** If BUSINESS ASSOCIATE receives, creates, transmits, or maintains EPH on behalf of COVERED ENTITY, BUSINESS ASSOCIATE will, in addition, do the following:

1. Develop, implement, maintain and use appropriate administrative, physical, and technical safeguards in compliance with Section 1173(d) of the Social Security Act, Title 42, Section 1320(d) or the United States Code and Title 45, Part 162 and 164 of CFR to preserve the integrity and confidentiality of all electronically maintained or transmitted PHI received from or on behalf of COVERED ENTITY.

2. Document and keep these security measures current and available for inspection by COVERED ENTITY.

3. Ensure that any agent, including a subcontractor, to whom the BUSINESS ASSOCIATE provides EPH agrees to implement reasonable and appropriate safeguards to protect it.

4. Report to the COVERED ENTITY any Security Incident of which it becomes aware. For the purposes of this Agreement, Security Incident means, as set forth in 45 C.F. R. section 164.304, “the attempted or successful unauthorized access, use, disclosure, modification, or destruction of information or interference with system operations in an information system.”
APPENDIX F - ASP SECURITY ASSESSMENT CHECKLIST
INSTRUCTIONS

The following checklist identifies the baseline security criteria that need to be considered when an ASP-based application solution is being evaluated. This checklist should be included in RFPs issued to ASP vendors when a Department is considering an ASP solution. The same checklist can also be used to evaluate the security of existing ASP implementations that may not have been subjected to a security review process prior to implementation. In both of these cases, the Department and the County CIO’s Office designee will review the vendor’s responses in order to determine whether adequate security is provided using the vendor’s proposed solution.

In general, the greater the risk involved in implementing an ASP model, the greater the requirement for demonstrating that the ASP is in compliance with County policies. For example, if electronic Protected Health Information (ePHI) data will be processed by the application, the much more stringent HIPAA regulations would apply. However, the following material is provided as suggestions for evaluating an ASP-based implementation, rather than as hard requirements in which each one must be complied with in full. The situation in each Department evaluating the use of an ASP implementation will be unique, and the overall security requirements for such an application should be based on the classification level of the data involved, on the Department’s unique business requirements, and on the overall security measures that are in place.

In asking vendors to complete the attached checklist, note that detailed responses are required, and not just simple “yes” or “no” answers. Enough information must be provided to allow a valid comparison between vendor practices and those required by the County.

Other “proof” that a particular ASP meets County security guidelines might include the following:

- A signed statement from the ASP vendor
- A signed attestation from a responsible third-party, such as a vendor specializing in conducting security audits/assessments
- Provision of a copy of any relevant documents (e.g., the required IT Security Policy and Business Continuity Plan)
APPENDIX H – SECURITY ASSESSMENT CHECKLIST

Offeror – please complete the attached checklist. Note that detailed responses are required, and not just simple “yes” or “no” answers. Complete detailed information must be provided to allow a valid comparison between supplier practices and those required by the COUNTY. The information provided below shall be accurate and true.

<table>
<thead>
<tr>
<th>COUNTY Policy Ref. #</th>
<th>Description of COUNTY Requirement</th>
<th>Details on How ASP Meets Requirement</th>
<th>Other Security Measures That Mitigate This Risk</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>16.3.4</td>
<td>The ASP has a written Disaster Recovery Plan that offers a viable approach to restoring operations following an emergency situation.</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>16.3.4a</td>
<td>The ASP site has adequate, redundant physical and/or logical network connectivity to ensure continued network connectivity to ensure continued operations following a network failure.</td>
<td></td>
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<tr>
<td>16.3.4b</td>
<td>The ASP performs system/application database backups on a schedule that is consistent with the importance of the Department application.</td>
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<tr>
<td>16.3.4b</td>
<td>Backup media are treated with a level of</td>
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Tissue Management System RFP #893
<table>
<thead>
<tr>
<th>COUNTY Policy Ref. #</th>
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<th>Other Security Measures That Mitigate This Risk</th>
<th>Comments</th>
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</thead>
<tbody>
<tr>
<td>security commensurate with the classification level of the data they contain.</td>
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<tr>
<td>16.3.4c</td>
<td>ASP servers are closely monitored for both performance and availability.</td>
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<tr>
<td>16.3.4d</td>
<td>The ASP is willing to sign a Service level Agreement (SLA) that is consistent with the importance of the Department application.</td>
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<tr>
<td>16.3.5</td>
<td>The ASP has a formal, written Security Policy.</td>
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</tr>
<tr>
<td>16.3.5a</td>
<td>COUNTY User authentication standards (both local and for remote access) can be implemented if COUNTY users access the application directly on the ASP server. For remote connections, this includes use of encrypted VPN connectivity and one-</td>
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<tr>
<td>COUNTY Policy Ref. #</td>
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<td>time password technology. Other mechanisms, such as secure SSL, may also be used in some circumstances as long as sole reliance is not placed on simple User ID/password combinations for authentication.</td>
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<tr>
<td>16.3.5b</td>
<td>Once granted access, Users are limited to authorized activities only; i.e., customers are prevented from accessing either applications or data that belong to other customers.</td>
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<tr>
<td>16.3.5c</td>
<td>ASP network connectivity is protected by firewalls, intrusion detection/prevention systems, etc. designed to protect against attack.</td>
<td></td>
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<tr>
<td>16.3.5d</td>
<td>The equipment hosting the Department’s application is located in a physically secure facility that employs</td>
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<tr>
<td>COUNTY Policy Ref. #</td>
<td>Description of COUNTY Requirement</td>
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<tr>
<td></td>
<td>access control measures, such as badges, card key access, or keypad entry systems.</td>
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<tr>
<td>16.3.5d</td>
<td>ASP servers are kept in locked areas/cages that limit access to authorized personnel.</td>
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<tr>
<td>16.3.5e</td>
<td>ASP staff is bonded, and/or have been subjected to background checks.</td>
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<tr>
<td>16.3.5f</td>
<td>ASP servers are hardened against attack and operating system and server software patches related to security are applied regularly.</td>
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<tr>
<td>16.3.5f</td>
<td>Commercially available anti-virus software is used on the servers, and is maintained in a current state.</td>
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<tr>
<td>16.3.5g</td>
<td>ASP servers are monitored on a continuous basis, and logs are kept of all activity.</td>
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<tr>
<td>16.3.5g</td>
<td>The ASP is willing to</td>
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<tr>
<td>COUNTY Policy Ref. #</td>
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<tr>
<td>16.3.5h, 16.3.5i</td>
<td>report security breaches and/or security issues to the COUNTY.</td>
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<tr>
<td>16.3.5h</td>
<td>The ASP conducts regular vulnerability assessments, using viable third-party organizations, designed to assess both the ASP’s network infrastructure and the individual servers that host applications. The ASP implements “fixes” to correct discovered vulnerabilities.</td>
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<tr>
<td>16.3.5i</td>
<td>The ASP has a formal Incident Response Plan.</td>
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<tr>
<td>N/A</td>
<td>(Optional) The network infrastructure hosting the Department application is “air-gapped” from any other network or customer that the ASP may have. This means that in an ideal situation, the</td>
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<td>COUNTY Policy Ref. #</td>
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<td>application environment must use a separate, dedicated server, as well as a separate network infrastructure.</td>
<td>N/A</td>
<td>N/A</td>
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</tr>
<tr>
<td>Section 13.0, Encryption</td>
<td>Encryption or hashing algorithms utilized by the ASP application infrastructure utilize algorithms that have been published and evaluated by the general cryptographic community.</td>
<td>N/A</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>N/A</td>
<td>The ASP is willing to permit on-site visits by COUNTY staff in order to evaluate security measures in place.</td>
<td>N/A</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>N/A</td>
<td>If the Department will be connecting to the ASP via a private connection (such as a dedicated T1 circuit), the circuit will terminate on the COUNTY’s extranet and operation of the circuit will fall within the policies related to network connections</td>
<td>N/A</td>
<td>N/A</td>
<td></td>
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<tr>
<td>COUNTY Policy Ref. #</td>
<td>Description of COUNTY Requirement</td>
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<td>from non-COUNTY entities. If a public network such as the Internet is used, the ASP deploys appropriate firewall technology, and the traffic between Santa Clara COUNTY and the ASP is protected and authenticated through the implementation of VPN or equivalent technology.</td>
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</table>

Completed by: ____________  
(Supplier’s name)

__________  
(Print Name)

__________  
(Signature)

__________  
(Title)

__________  
(Date)

Approved by: County of Santa Clara Information Services Dept.

__________  
(Print Name)

__________  
(Signature)

__________  
(Title)

__________  
(Date)
APPENDIX G
TECHNICAL, FUNCTIONAL, INTEGRATION REQUIREMENTS AND RESPONSE FORM

A. TECHNICAL REQUIREMENTS

1. Description of System

   a. Offerors must provide a description of the proposed product, database, software and services, including how the proposed system will meet or exceed the requirements stated in the entire RFP. Include sufficient technical information about the application, operating environment and performance data to enable the County to determine whether or not the proposed system meets the technical environment prerequisites.

   b. Offerors must identify/list all software required for the solution that is not supplied directly by the Offeror (any/all third party software).

   c. Offerors must provide an overview and/or benchmarks relating to the system’s ability to process information in real time. Include the number of concurrent users as well as named users the proposed system will accommodate and state the maximum number of recommended users.

   d. Offerors must identify any requirement to purchase interfaces from other vendors to work with the proposed solution.

   e. Offerors must define the scalability of the proposed system.
      1. Can the system be purchased in modules and expanded?
      2. How scalable is the proposed software regarding the number of users?
      3. Does the system scale in parallel, i.e. can additional application servers be configured in a load-balanced cluster?
      4. Can the database, application and data analysis components be configured to reside on separate independent servers, so that one impacted subsystem does not affect the overall solution?

   f. Offerors must identify how many users are can access the proposed system. (Concurrent users).
g. Offerors must identify if the proposed software is COM (Component Object Model) compliant.

h. Offerors must identify if the proposed software is ODBC, OLE-DB or OLAP compliant. Identify any drivers provided.

i. Offeror must describe licenses required for the software (concurrent / per seat and the number associated).

j. Offeror must describe how the system protects database records while it is being accessed by one user, so that multiple users will not attempt to change the record at the same time.

k. Offeror must identify if the solution’s database is ACID (Atomicity, Consistency, Isolation and Durability) compliant, and how it provides transaction rollback capability in the event of a failed transaction.

l. Offer must define the requirements for a test system. Include all related components (hardware, software, etc.) Include test system costs.

m. Offeror must describe the maximum number of database records that can be stored.

n. Offeror must define which third party reporting tools the system is compatible with the proposed system.

o. Offeror must describe the ability to test interfaces to the HIS system.

p. Offeror must provide the data dictionary and schema with the system.

q. Offeror must describe the minimum monitor and screen resolution limit.

r. Offeror must describe the process for change management or customer notification.

s. Offeror must describe the current version number and release date, including how often target dates are met.

t. Offeror must provide continuous application and system support 24 hours a day, 365 days per year.
u. Offeror must provide the company escalation and response plan, and describe how issues are triaged and escalated.

v. Offeror must provide the average response time of the proposed system.

w. Offeror must describe the level of customization available without a programmer or vendor support.

x. Offeror must provide the location of the closest service representative.

y. Define the system uptime. Include planned downtime windows.

2. **Equipment and Software**

a. Offeror must provide detailed workstation hardware specifications, including but not limited to, operating system, RAM, size of the hard drive, type of monitors, barcode devices, scanning devices, barcode printing devices, etc.

b. Offeror should describe how the client software components are able to coexist with other software and applications on end-user workstations.

c. Describe the reporting software compatible with the proposed system. (Crystal, Excel, Access, etc.)

3. **Backup/Recovery**

a. Offeror must describe the backup capabilities for the proposed system, including:
   1. Process for how backups are performed
   2. Process for Tenant-initiated backups for critical data
   3. Service availability guarantee

b. Offeror must describe the Disaster Recovery plan, including requirements for zero-downtime.

c. Offeror should describe the notification provided if an application failure occurs.
d. Offeror must describe the process for automatic reprogramming and/or recovery after a failure due to hardware, software or absence of power.

e. Describe the capabilities for periodically exporting data stored in the database, and if it can be exported to MS Excel, MS Access or other software.

4. **Network/Hardware**

a. Offeror must provide a system/network design diagram, which provides a visual summary of the system’s servers, network and ancillary components and their relationships.

b. Offeror must describe any proprietary equipment utilized.

c. Offeror must describe any special networking requirements, i.e. dedicated/segregated network segments, VLANs, etc.

d. Offeror must describe the response time expected with the proposed system.

5. **Storage**

a. Offeror must explain how data is archived (e.g., on demand, automatically, via optical disk, etc.), and the capabilities of the system for storing a minimum of 10 years beyond the date of Distribution, date of transplantation (if known), date of disposition, or date of expiration of the tissue (whichever is latest) or longer if required by applicable federal, state, and/or local laws and/or regulations. Also describe how the records are maintained in a manner to preserve their completeness and accuracy over time.

b. Offeror should describe how the system will store the data on non-proprietary media and in an industry-standard format. Offeror should also specify the type of media used for long-term storage and the format in which it is stored.

c. Offeror must describe the archival scheme for the system, including the recommended length of time data is retained on the production system and the availability of data for reporting after archiving.

d. Offeror must describe the maximum size of the database and the largest currently operating production and archive directories.
e. Offeror must describe the long-term storage options available for the system.

f. Offeror must describe how the system will print tissue record information on demand. Offeror must specify any special hardware or required printers necessary for printing.

g. How is the data stored within the database? Can it be stored in a separate database?

6. **Data Management**

a. Describe the data management approach.

b. Is the data stored in separate databases?

c. Provide a copy of the Service Level Agreement.

7. **Integration**

a. Offeror should define the system’s capability to support multiple browser types (i.e. Internet Explorer, Mozilla Firefox, and Opera) on different platforms, and the minimum version of each browser supported if the system supports web-based access.

b. Offeror should specify all browser plug-ins necessary to utilize web-based features.

c. Offeror should specify the web service standards used and the functionality exposed through the web services, if the system supports the use of web service protocols such as SOAP.

d. Offeror must complete the Security Assessment Checklist.

e. Offeror must describe if the system can integrate with the existing Perioperative surgical information system via outbound HL7 interface.
8. **Critical Updates, Patches and Antivirus**

   a. Offeror must describe the process for approving and installing operating system Critical Updates. Attach the offeror policy regarding Microsoft Critical Updates.

   b. Offeror must describe or attach the company Service Pack policy for the proposed solution.

   c. Offeror must describe the Antivirus software used to protect data in real-time on the vendor’s servers.

   d. Offeror must describe any issues that may occur when running Antivirus software in real-time on the workstations.

   e. Offeror must describe or attach the company policy regarding the use of anti-virus software with the proposed system.

   f. Offeror must describe the disclosure policies related to security vulnerabilities found in the system, including procedures in place to notify customers of potential flaws, and the average time between a flaw being discovered and corrective action taken.

9. **Application Security Features**

   a. Offeror should describe the system’s compliance with LDAP (Lightweight Directory Access Protocol), and how the system can be configured to authenticate users against it.

   b. Offeror should describe how the proposed solution can be configured to authenticate users against an Active Directory 2003 tree, if possible.

   c. Offeror should describe how the solution audits user access and privilege use and the information that is logged.

   d. Offeror should describe how the solution allows the County to configure minimum password difficulty requirements, and password lockout policies.
e. Offeror should describe how the solution allows system administrators to set a password expiration policy, thereby requiring end-users to change their passwords at a specified interval.

f. Offeror should describe how the solution encrypts sensitive information transmitted across the network and internet, and specify the algorithms used.

g. Offeror should specify whether the system establishes user identity via:

1. A user ID and password; or
2. Two-factor authentication, such as a smart-card and a PIN. If two-factor authentication is available or used, offeror must describe the hardware requirements, the authentication process, and any supplies needed for ongoing implementation.

h. Offeror should describe how access privileges are configured in the system, and whether or not privileges can be based on group designations.

i. Offeror should describe how different levels of security and privileges are established.

j. Offeror should specify if a “user inactivity timeout” feature is available that forces a user to re-authenticate if idle for a preconfigured amount of time.

k. Offeror must describe how the system utilizes electronic signatures and electronic confirmation.
B. FUNCTIONAL AND INTEGRATION REQUIREMENTS RESPONSE FORM

OFFEROR NAME: ________________________________

Response Code: Respondent should place the appropriate letter designation in the “Availability” column according to the following codes and their description:

A. Specification is one that currently exists in the proposed software in the current production version

B. Specification is not in the proposed software but is a planned enhancement or will be added at no additional cost.

C. Specification is not part of the proposed software but will be added at additional cost included in the County’s price. All such additional costs must be reported on an attachment to the cost response form.

D. Specification is not available in the proposed software.

Reference: Please provide any additional information requested or any additional information useful to the proposal in the comments column. If referencing attachments or other included information, write the location (Binder/Section/Page Number) of the discussion of the specification in the offeror’s proposal. Technical materials may be submitted as part of the proposal, and should be clearly labeled as such.

<table>
<thead>
<tr>
<th>#</th>
<th>Description</th>
<th>Availability</th>
<th>Comments or Page and Binder Number in the proposal where additional information can be found (Include delivery date if Availability is “B” or “C”)</th>
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<tbody>
<tr>
<td></td>
<td>Tissue Management System Data</td>
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</table>
| 1. | Does the system capture the following elements?  
   a. FDA registration  
   b. Copies of FDA registration and AATB accreditation of outside vendors from whom tissue is obtained (EBAA for |
<table>
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<tr>
<th>#</th>
<th>Description</th>
<th>Availability</th>
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</thead>
</table>
|  | ocular use tissue, AABB for stem cells)  
c. Listing of all tissue products ordered, stored and used  
d. Informed consent documents  
e. Donor suitability assessment criteria  
f. Recovery  
g. Processing  
h. Preservation  
i. Labeling  
j. Storage  
k. Quarantining  
l. Testing record review  
m. Releasing  
n. Distribution  
o. Ordering and receipt of tissue acquired from other sources  
p. Instructions/procedures for reconstitution  
q. Identity of personnel preparing, accepting and issuing tissue  
r. Dates and times of preparing, accepting, and issuing tissue  
s. Quality management records  
t. Recall criteria and procedures  
u. Disposal of tissue | |
<p>| 2. | Describe how the system provides a letter of notification or email back to the tissue bank to notify who got the implant. | |
| 3. | Describe how the system records tissue banks registered with the FDA and licensed by State agencies. | |
| 4. | Describe how the system captures the | |</p>
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<th>#</th>
<th>Description</th>
<th>Availability</th>
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<tr>
<td></td>
<td>following information:</td>
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<td></td>
<td>a. time of receipt to final disposition</td>
<td></td>
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<td></td>
<td>b. time and identification of person handling tissue, for receipt, transfer, storage removal, preparation</td>
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<td></td>
<td>c. Vendors CA Tissue Banking License</td>
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<td>5.</td>
<td>Describe how the system meets ALL FDA requirements.</td>
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<td>6.</td>
<td>Describe how the system meets ALL CDPH requirements.</td>
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<tr>
<td>7.</td>
<td>Describe how the system meets ALL TJC requirements.</td>
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<tr>
<td>8.</td>
<td>Describe the process or electronic record retrieval.</td>
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<td>9.</td>
<td>Describe the system’s ability to store scanned or downloaded documents for viewing.</td>
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<tr>
<td>10.</td>
<td>Describe the ability to track and record accreditation and by which agency.</td>
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<tr>
<td>11.</td>
<td>Describe how the system notifies staff when a certification needs to be renewed.</td>
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<tr>
<td>12.</td>
<td>Describe how the system stores the source facility and manufacturer’s written instructions in the system for viewing.</td>
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<tr>
<td>13.</td>
<td>Describe how the system documents the following:</td>
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<tr>
<td></td>
<td>a. Freezer Failure</td>
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<td>b. Freezer Temperature</td>
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<td></td>
<td>c. Tissue handling</td>
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<td>#</td>
<td>Description</td>
<td>Availability</td>
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<tr>
<td></td>
<td>d. Auditing</td>
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<td></td>
<td>e. Receipt</td>
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<td></td>
<td>f. Storage</td>
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<tr>
<td></td>
<td>g. Collection of Autograft tissue</td>
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<td></td>
<td>h. Disposing of Tissue</td>
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<tr>
<td></td>
<td>i. Reconciliation</td>
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<tr>
<td></td>
<td>j. Biological Tissue Preparation</td>
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<tr>
<td></td>
<td>k. Recall, Adverse Reaction, or Notification of Infectious Disease</td>
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<td>14. Describe how the system implant information is kept and for how long.</td>
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<td></td>
<td>Can the information be retrieved if archived?</td>
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<td></td>
<td>15. Describe how the system sorts inventory. (i.e. expiration date, vendor,</td>
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<td></td>
<td>type, etc.)</td>
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<td>16. Describe how the system alerts for expired and recalled products. (i.e.</td>
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<td></td>
<td>email, online notification, etc.)</td>
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<td>17. Describe how the system provides notification of distributor/vendor final</td>
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<td></td>
<td>disposition.</td>
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<td>18. Describe the system log-in process and security. (unique logins/passwords)</td>
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<td>19. Describe the audit trail for users accessing the system. (i.e. record</td>
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<td></td>
<td>access, field updates, etc.)</td>
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<td>20. Describe how the system supports multiple user profiles, and limits</td>
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<td></td>
<td>access by user profile. Indicate the number of profiles allowed.</td>
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<td></td>
<td>21. Describe how the data is password protected.</td>
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<td>22. Describe how the system documents the</td>
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<tr>
<td>#</td>
<td>Description</td>
<td>Availability</td>
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<td></td>
<td>tissue implant information.</td>
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<td>23.</td>
<td>Does the system support bar coding? If so, provide specifications. Indicate if 2D or 3D.</td>
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<td>24.</td>
<td>Describe if the system can print unique barcode labels.</td>
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<td>25.</td>
<td>Describe how the regulatory status of tissue suppliers is maintained and displayed.</td>
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<td>26.</td>
<td>Describe how the system performs inventory control. (i.e. alerts for replenishment, etc.)</td>
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<td>27.</td>
<td>Describe how many and which fields can be user-defined.</td>
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<td>28.</td>
<td>Describe how the system maintains autologous cell and tissue records.</td>
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<td>29.</td>
<td>Describe how the system identifies cells and tissue by unique identifier.</td>
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<td>30.</td>
<td>Describe how the system retrieves record information and prints hard copy records for review during inspection.</td>
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<td>31.</td>
<td>Describe how the system identifies cells and/or tissue by use of a unique identifier, dates and identities of staff involved in each significant step of the operation from retrieval through final disposition of the cells and/or tissue.</td>
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<td>32.</td>
<td>Describe how record revisions are handled. (lined through, initialed, date stamped, etc.)</td>
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<td></td>
<td><strong>Search</strong></td>
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<td>33.</td>
<td>Describe how implant information is accessible through the following search</td>
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<tr>
<td>#</td>
<td>Description</td>
<td>Availability</td>
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<td><strong>Criteria:</strong></td>
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<td></td>
<td>a. MRN/Patient ID Search</td>
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<td></td>
<td>b. Lot Number Search</td>
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<td></td>
<td>c. Tissue Number Search</td>
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<td>d. Expiration Date Search</td>
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<td></td>
<td>e. Manufacturer Search</td>
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<td>f. Product Type Search</td>
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<td>g. Storage Method Search</td>
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<td>h. Physician Name Search</td>
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<td>i. Date of Tissue Implant Search</td>
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<td><strong>Reports</strong></td>
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<td>34.</td>
<td><strong>Describe the ability to export data to MS Excel, MS Access and other programs.</strong></td>
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<td>35.</td>
<td><strong>Describe the reporting capabilities for the following:</strong></td>
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<tr>
<td></td>
<td>a. Product Inventory Report</td>
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<td></td>
<td>b. Tissue Implant Record</td>
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<td></td>
<td>c. Adverse Event Reporting to Patient and Supplier</td>
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<td></td>
<td>d. Custom reporting abilities</td>
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<td></td>
<td>e. Daily Temperature Log</td>
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<td>37.</td>
<td><strong>Describe the ability to print or email an item detail report to the manufacturer</strong></td>
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<tr>
<td>ID</td>
<td>QUESTION</td>
<td>ANSWER</td>
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<td>1</td>
<td>List the type of interfaces offered and classify them based on the choices below:</td>
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<td></td>
<td>b. Push model (vendor receives unsolicited messages, e.g. ADT)</td>
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<td></td>
<td>c. Pull model (vendor sends unsolicited messages, e.g. Charges)</td>
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<td></td>
<td>d. Query/Response model (query is sent from vendor and response is sent back)</td>
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<td>2</td>
<td>Is the HL7 (Version 2.x) standard supported? If so, which version?</td>
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<td>3</td>
<td>If the HL7 (Version 2.x) standard is supported what events are accepted?</td>
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<td>4</td>
<td>Does the system interface to:</td>
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<td>· Surgical Information Systems (SIS)</td>
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<td>5</td>
<td>Is the OPENLink Interface Engine used? If not, what Interface Engine is used and/or supported?</td>
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<td>6</td>
<td>Can data be sent/received real-time, batch, and file?</td>
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</table>
### TISSUE MANAGEMENT SYSTEM

**OFFEROR NAME:**

---

<table>
<thead>
<tr>
<th>Interface Provided (ADT, Charge, etc.)</th>
<th>Format (HL7, Fixed, ASCII, etc.)</th>
<th>Version / Variant</th>
<th>Connectivity Type (TCP/IP, SNA, etc.)</th>
<th>Freq (Real Time, Batch)</th>
<th># of connections</th>
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**Comments:**

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<th>8</th>
<th>Provide any additional information:</th>
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What is the format or standard type of data transmitted on each connection type?

Provide any additional information:
APPENDIX H
DECLARATION OF LOCAL BUSINESS

Santa Clara County gives local businesses a preference in formal solicitations of goods and services as set forth in the Board Policy, Section 5.3.13. A Bidder has the option of qualifying for the preference policy by self-declaring its qualification as a “local business.” By signing below, the bidder is certifying its qualification as a “local business” for purposes of application of Santa Clara County’s policy.

All information submitted is subject to investigation, as well as to disclosure to third parties under the California Public Records Act. Incomplete, unclear, or incomprehensible responses to the following will result in your bid not being considered for application of Santa Clara County’s local preference policy. False or dishonest responses will result in rejection of your bid or proposal and curtail your ability to conduct business with the County in the future. It may also result in legal action.

Please provide the complete physical address of your business with meaningful “production capability” located within the boundary of the County of Santa Clara. The term “production capability” means sales, marketing, manufacturing, servicing, or research and development capability that substantially and directly enhances the firm’s or bidder’s ability to perform the proposed contract. Post Office box numbers and/or residential addresses may not be used as the sole bases for establishing status as a “Local Business.” If you do not have a physical address in Santa Clara County, please indicate so, by writing “N/A.” If you have more than one physical address in Santa Clara County, please provide an attachment with all of the addresses in the form specified below.

Business
Name: ____________________________

Street: ____________________________

City/State: _________________________ Zip Code: ______________
Please Indicate Business Organization (Check One)

☐ Individual Proprietorship     ☐ Corporation

☐ Partnership                  ☐ Other

Bidder declares qualification as a local business as defined in County of Santa Clara Board Policy, Section 5.3.13.

I declare under penalty of perjury, under the laws of the State of California, that all statements contained in this Exhibit are true and correct, with full knowledge that all statements made in this application are subject to investigation and that any incomplete, unclear, false or dishonest response may be grounds for denial or revocation of the accompanying bid or proposal and may result in being barred from doing business with Santa Clara County and additional legal consequences.

________________________________________  _________________
Signature                           Title

________________________________________
Name                           Date

________________________________________
Tax ID Number                           Business License Number (if applicable)

[ONLY a declaration by the CEO, president or other highest executive officer of the company will be accepted for the purpose of determination of application of Santa Clara’s local preference policy.]