



DEPARTMENT OF HEALTH SERVICES

REQUEST FOR SERVICES (RFS)

FOR

INSTITUTIONAL REVIEW BOARD SERVICES

RFS No. PATSMA-DHS-006

October 2020

**Prepared By
Contracts and Grants Division**

**REQUEST FOR SERVICES (RFS)
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REQUEST FOR SERVICES INSTITUTIONAL REVIEW BOARD SERVICES

1.0 REQUEST FOR SERVICES TIMELINE

County Department: Department of Health Services (“DHS” or “Department”)

Request for Services (RFS) Number: PATSMA-DHS-006

Release Date: October 15, 2020

Written Questions Due Date: October 23, 2020 by 11:00 a.m. Pacific Standard Time (PST)

Solicitation Requirements Review: October 23, 2020 by 11:00 a.m. PST

Response Due Date and Time: November 2, 2020 by 11:00 a.m. PST

2.0 INTRODUCTION AND PROCESS

DHS is soliciting qualified consultants for the provision of Institutional Review Board Services (IRB) for the Emergency Medical Services (EMS) Agency and the EMS Consortium. Through this Request For Services (RFS), DHS intends to award and execute a Work Order to a qualified vendor under the Professional and Technical Services Master Agreement (PAT SMA).

This RFS offers a unique and exciting contracting opportunity for a highly qualified and motivated Vendor interested in working with the largest EMS system in the nation, comprised of the EMS Agency, twenty-nine (29) EMS provider agencies and seventy (70) hospitals with emergency services that receive 9-1-1 transports.

All interested Vendors must have an executed PAT SMA prior to being awarded of a Work Order. Interested Vendors that do not have a current status as a PAT SMA contractor may respond to this RFS if they submit a Response to DHS’ RFQ for PAT SMA and are issued a PAT SMA. The RFQ is available on the DHS Contracts and Grants Portal at <https://dhs.lacounty.gov/cg>.

3.0 SCOPE OF SERVICES

3.1 Background

The EMS Agency oversees the EMS system in Los Angeles County. The EMS Agency is responsible for the coordination, planning and regulation of

the countywide EMS System. This work is accomplished in coordination with the EMS provider agencies and 9-1-1 receiving hospitals and includes the following activities:

- Designating hospital specialty centers to include Trauma – Adult and Pediatric, ST Elevation Myocardial Infarction, Cardiac Arrest, Stroke – Primary and Comprehensive, Emergency Departments Approved for Pediatrics, Pediatric Medical Centers, Sexual Assault Response Team providers, Base Hospitals, Perinatal, Burn, and Hospital Preparedness Program participants.
- Providing medical control and assuring medical accountability throughout the EMS system through the development of treatment protocols and medical control guidelines used by the over 4,000 licensed paramedics, 8,000 emergency medical technicians (EMT) and 900 Mobile Intensive Care Nurses (MICN) in providing care to persons who call 9-1-1
- On-going quality improvement
- Prehospital Care Research
- Licensing of private ambulance companies
- Certifying EMTs and taking disciplinary action on their certification when indicated, certification of MICNs and local accreditation of paramedics
- Approving paramedic, EMT, public safety and continuing education training programs
- Managing the physician and hospital reimbursement programs for indigent emergency care
- Coordinating healthcare disaster preparedness, response and recovery activities

3.2 Purpose

The FDA requires that an Institutional Review Board (IRB) review and have authority to approve, require modifications in, or disapprove all research activities covered by the IRB regulations [21 Code of Federal Regulation (CFR) 56.109(a)]. An IRB is required to ensure that appropriate safeguards exist to protect the rights and welfare of research subjects [21 CFR 56.107(a) and 56.111]. Through this RFS, the County seeks to identify and select a qualified vendor that will provide the necessary review for all research projects conducted by the EMS Agency and all EMS system participants. Attachment A provides a listing of all current EMS system participants subject to this RFS. The selected Vendor will serve as the IRB of record for EMS Agency coordinated research and will serve as the IRB for Consortium studies involving one or more EMS system participants.

3.3 Services

3.3.1 Specific Work

The selected Vendor will be responsible for, and complying with, Title 21, Chapter I, Subchapter A, Part 56 – Institutional Review Boards, and including, but not limited to, the following:

- Conduct initial review of each research study
- Ensure assigned consultant is knowledgeable of local research context, by conducting on-site visits and meetings including video or teleconferencing options
- Review all subject information and consent documents
- Provide assurances that all human subject research activities comply with federal laws, regulations, policies and guidelines.
- Review Site-specific materials, including a completed Site-Specific submission form
- Provide continuous oversight of each Study it approves
- Conduct continuing review of each approved Study at intervals appropriate to the degree of risk in Study but not less than once per year
- Provide timely notices to the Federal Drug Administration (FDA) or the United States Health and Human Services (HHS) Office for Human Research Protections (OHRP) as required by applicable law, such as unanticipated problems involving risks to subjects or others, any serious or continuing noncompliance with FDA or HHS regulations or suspension or termination of IRB approval.
- Provide support for implementation of large clinical trials including those implemented under Exception From Informed Consent (EFIC).
- Be the IRB of record for the Federal Wide Assurance with the OHRP.
- Provide coordination of IRB approvals for clinical trials within the consortium, as well as with a Data Coordinating Center, as applicable.
- Provide timely notices to the Principal Investigator and applicable Study Site of unanticipated problems involving risks to subjects

or others, any serious or continuing noncompliance with FDA or HHS regulations or suspension or termination of IRB approval.

3.3.2 IRB Service Phases

The IRB services will consist of the following two phases:

Phase 1- Will consist of enrolling EMS system participants as Consortium members to facilitate participation in EMS research.

The selected Vendor will contact all EMS system participants listed on Attachment A, and work directly with their organization to enroll them as Consortium members and obtain required signatures to the IRB specific participation agreement

Phase 2- Will consist of providing IRB services as listed in 3.3.1 above when an actual research study is conducted in Los Angeles County by the EMS Agency and the Consortium members.

3.3.3 Deliverables

The selected Vendor shall provide the following deliverables:

- Negotiate participation agreement with EMS system participants to facilitate their participation in research studies conducted by the EMS Agency.
- Serve as the EMS Agency IRB and be responsible for initial and continuing review of studies conducted by the EMS Agency.
- Negotiate the written assurance for any and all research studies with the HHS.

4.0 MINIMUM REQUIREMENTS

Interested Vendors that can demonstrate their ability to provide the services in RFS, Section 3.0 - Scope of Services, are encouraged to respond to this solicitation, provided they meet the following minimum qualifications:

4.1 A) Vendor must have a current status as a PATSMA contractor

OR

B) Vendors that do not have a current status as a PATSMA contractor may respond to this RFS if they submit a Response to DHS' RFQ for PATSMA and are issued a PATSMA. Vendors must respond to BOTH the RFQ and this RFS by November 2, 2020, no later than 11 A.M PST.

The RFQ can be found at: <http://cg.dhs.lacounty.gov/>.

- 4.2 The Vendor or the Vendor's principal (i.e. President, Vice President, Chief Executive Officer CEO, or Director) must have served as an IRB for a minimum of one (1) engagement within the last three (3) years in an EMS system research study including those conducted locally, regionally, or nationally.
- 4.3 The Vendor must provide evidence of providing IRB services in a minimum of one (1) engagement within the last three (3) years for an EMS or non-EMS research study that included Exception from Informed Consent (EFIC), conducted locally, regionally, or nationally
- 4.4 **(This requirement only applies to Vendors that have had a County contract reviewed by the County's Department of the Auditor-Controller within the last 10 years).** Vendor does not have unresolved questioned costs identified by the Department of the Auditor-Controller, in an amount over \$100,000, that are confirmed to be disallowed costs by the contracting County department, and remain unpaid for six months or more from the date of disallowance, unless such disallowed costs are the subject of current good faith negotiations to resolve the disallowed costs, in the opinion of the County.

5.0 WORK ORDER TERM

The Work Order Term is anticipated to be five (5) years, with an option to extend on a six-month basis for up to two (2) additional years at the County's sole discretion. The County reserves the right to extend the term of the resultant Work Order, at its sole discretion, to allow the selected vendor additional time to complete and provide all deliverables, at no additional cost to the County.

6.0 SPECIFIC PROVISIONS

The table below indicates whether additional provisions and/or Exhibits will be required.

Yes	No	Specific Provisions/Exhibits
	X	Business Associate Agreement
	X	Information Security Requirements
	X	Additional Insurance Requirements

7.0 CONTACT WITH COUNTY PERSONNEL

All communication regarding this Solicitation or any matter relating thereto must be in writing and e-mailed to the following:

PATSMA Administrator
E-mail address: PATSMA@dhs.lacounty.gov

8.0 VENDOR'S QUESTIONS

8.1 Vendors may submit written questions regarding this solicitation to the e-mail address identified in Section 7.0 - Contact with County Personnel. All questions submitted will be compiled, without identifying the submitting Vendor and, along with the appropriate answers, will be issued as an addendum to the RFS and made available on the DHS Contracts and Grants Portal at <http://cg.dhs.lacounty.gov/>.

8.2 When submitting questions, identify the solicitation title and number in the subject line. The body of the e-mail should indicate the solicitation section number and page number and quote the language that prompted the question. The County reserves the right to group similar questions when providing answers. Any questions regarding the solicitation process after the initial due date and time may be submitted to the contact listed in Section 7.0 Contact with County Personnel.

9.0 SOLICITATION REQUIREMENTS REVIEW

Any person or entity may seek a Solicitation Requirements Review by submitting Attachment B - Transmittal Form to Request a Solicitation Requirements Review to the Department conducting the solicitation as described in this Section. A request for a Solicitation Requirements Review may be denied, in the Department's sole discretion, if the request does not satisfy all the following criteria:

1. The request is made within the time frame identified in Section 1.0 - Request For Services Timeline;
2. The request includes documentation (e.g., letterhead, business card, etc.), which identifies the underlying authority of the person or entity to submit a Response;
3. The request itemizes in appropriate detail, each matter contested and factual reasons for the requested review; and
4. The request asserts that either:
 - a. application of the minimum qualifications, review criteria and/or business requirements unfairly disadvantages the person or entity; or,
 - b. due to unclear instructions, the process may result in the County not

receiving the best possible responses from prospective Vendors.

Requests for a Solicitation Requirements Review not satisfying all of these criteria may, in the Department's sole discretion, be denied. The Solicitation Requirements Review shall be completed and the Department's determination shall be provided to the requesting person or entity, in writing, within a reasonable time prior to the Response due date.

10.0 SUBMISSION INSTRUCTIONS

The Vendor shall email one (1) Response to the e-mail address listed in Section 7.0 - Contact with County Personnel, by the Response Due Date and Time identified in Section 1.0 - Request For Services Timeline. It is the sole responsibility of the submitting Vendor to ensure that its solicitation response is received before the submission deadline.

11.0 TRUTH AND ACCURACY OF REPRESENTATIONS

False, misleading, incomplete, or deceptively unresponsive statements in connection with any Response shall be sufficient cause for rejection of the Response. The review and determination in this area shall be at the sole judgment of the Director of Health Services and his/her judgment shall be final. A Vendor who is disqualified pursuant to this Section 11.0 may be debarred from working with the County.

12.0 VENDOR'S RESPONSE

The RFS Response shall be submitted in PDF format, and shall contain the following content and be prepared in the following sequence:

12.1 Cover Letter

Cover Letter on Vendor's letterhead. The letter shall be a maximum of **one page** in length and must include:

- RFS title and number, indicated in Section 1.0 - RFS Timeline
- Vendor's name and address
- Name, address, telephone number, and e-mail address of the person authorized to make representations for the Vendor.

12.2 Table of Contents

The Table of Contents must be a comprehensive listing of materials included in the RFS. This section must include a clear definition of the material identified by sequential page numbers and by section reference numbers.

12.3 Vendor's Minimum Qualifications

Provide a narrative that demonstrates your firm or corporation meets the minimum qualifications in RFS, Section 4.0 - Minimum Qualifications, including a description of relevant project(s) and background information, with project(s) dates and locations.

12.4 Vendor's Personnel and Experience

Provide an organizational chart/list and resumes of key personnel that will be responsible for the delivery of services and their roles. Include relevant experience, professional certifications/licenses, education, training, special skills and other abilities to successfully perform the required services, as described in RFS, Section 3.0 - Scope of Services.

12.5 Vendor's Approach and Methodology

Provide a detailed description of your approach and methodology to provide the IRB consulting services for the EMS Agency as described in Section 3.0 - Scope of Services. Ensure your response includes a project plan with timelines, a detailed explanation for accomplishing the specific work and deliverables. The response should also include sufficient detail to enable the County to:

1. Determine if the Vendor has a good understanding of the project scope and deliverables; and
2. Assess the appropriateness of the proposed strategies, procedures and techniques to be used.

Reference to or repetition of the requirements from this RFS does not constitute a "good understanding." Complete, yet concise, supplementary strategies, procedures, methods, explanations, and descriptions are also required to make possible the County's review as to the Vendor's understanding.

12.6 Vendor's Budget

Complete Attachment C – Budget, by providing a breakdown of all direct and indirect costs associated with performing the tasks required to support your funding as described in RFS, Section 3.0 - Scope of Work.

12.7 Vendor's References

Provide two (2) reference for projects that were provided in RFS, Section 12.3 - Vendor's Minimum Qualifications, by completing Attachment D – Project Reference.

It is the Vendors' sole responsibility to ensure that the reference contact name, phone number, and e-mail address is accurate and that all fields identified on Attachment D - Project Reference are completed.

County may disqualify a Vendor if:

- Reference fails to substantiate that the Vendor, as an entity, provided the services; or
- Reference fails to substantiate the Vendor's description of the services provided; or
- Reference fails to support that the Vendor has a continuing pattern of providing capable, productive and skilled personnel; or
- DHS is unable to reach the point of contact with reasonable effort. It is the Vendor's responsibility to inform their references' point of contact of County's normal working hours- Monday through Friday, 8 a.m. – 5 p.m. PST.

13.0 REVIEW AND SELECTION PROCESS

The County reserves the sole right to exercise its discretionary judgment concerning the selection and review of the contents of the Responses submitted pursuant to this RFS.

As a result of this RFS, the County may:

- 1) Request further information, documents, presentations, and/or conference call or in-person interviews substantiating Vendors' qualifications, experience, and readiness to provide the services described in the RFS;
- 2) Enter into contract negotiations based on Vendor's submission; and/or
- 3) Take no further action at this time on this matter.

13.1 Response Selection Process

The selection process will begin with receipt of the Response. Review of the Responses will be made by a Review Committee selected by DHS. The Review Committee will conduct a comparative review of all Responses based on the criteria listed below and rank the Responses in numerical sequence. The top ranked Vendor will be selected to perform the services described in this RFS and in accordance with the Vendor's submitted Response.

13.1.1 Phase One - (Pass/Fail)

13.1.1a Adherence to the Minimum Qualifications

During Phase One, a pass/fail review will be made of the Responses to determine compliance with the Vendor's Minimum Qualifications as indicated in Section 12.3 of this RFS. Failure of the Vendor to comply and demonstrate that it meets the Minimum Qualifications may result in its Response being disqualified without further review and consideration in the County's sole discretion. The pass/fail criteria are:

Response was received by the Response Due Date and Time.

Vendor meets the Minimum Qualifications as set forth in RFS, Section 12.3

13.1.1b Verification Process

A review will be conducted of the Vendor's business status by checking with all applicable databases and the reference submitted in Attachment D – Project Reference. The review may include, but not be limited to, databases available with the California Secretary of State – Business Programs; California State's Suspended and Ineligible Provider List for Medi-Cal, Federal Debarment List, Federal System for Award Management, and if applicable, a review of the Auditor Controller's Intranet website and Contractor Alert Reporting Database reflecting past performance history on County contracts.

13.1.2 Phase Two – Review of Written Material (100%)

- The Vendor's response to Section 12.4 – Vendor's Personnel and Experience, will be evaluated based on the appropriateness and suitability of the credentials and experience of the Vendor's identified staff.
- The Vendor's response to Section 12.5 – Vendor's Approach and Methodology, will be evaluated based on the appropriateness and suitability of the Vendor's understanding of the project scope and deliverables, and its proposed strategies, procedures and techniques to be used.

- A review will be conducted on the appropriateness of the Vendor's response to Attachment C – Budget.

13.3 Disqualification Review

A Response may be disqualified from consideration because the Department determined, in its discretionary judgment, that the Response was non-responsive at any time during the review process. If the Department determines that a Response is disqualified due to non-responsiveness, the Department will notify the Vendor in writing.

Upon receipt of a written determination of non-responsiveness, the Vendor may submit a written request for a Disqualification Review within the timeframe specified in the written determination.

A request for a Disqualification Review may, in the Department's sole discretion, be denied if the request does not satisfy all of the following criteria:

1. The request for a Disqualification Review is submitted within the timeframe specified in the written determination; and
2. The request for a Disqualification Review asserts that the Department's disqualification of the Response was erroneous (e.g., factual error, etc.) and provides factual support on each ground asserted, as well as copies of all documents and other material that support the assertion(s).

Any Request for Disqualification Review not satisfying all these criteria may, in the Department's sole discretion, be denied. The Disqualification Review shall be completed and the determination shall be provided to the requesting Vendor, in writing, prior to the conclusion of the selection process.

13.4. County's Option to Reject Responses

Vendors are hereby advised that this RFS is a solicitation for Responses only, and is not intended, and is not to be construed as a promise to engage in negotiations pursuant to any statute, ordinance, rule, or regulation. The Department may, at its sole discretion, reject any or all Responses to this RFS or may, in its sole discretion, reject all Responses and cancel this RFS in its entirety. The Department and County of Los Angeles shall not be liable for any costs incurred by the proposer in connection with the preparation and submission of any proposal. The Department and County of Los Angeles reserves the right to waive inconsequential disparities in a submitted proposal.

14.0 APPEAL RIGHTS

14.1 Debriefing Process

14.1.1 Upon completion of the review, the Department will notify the remaining Vendors in writing that the Department is entering negotiations with the selected Vendor. Upon receipt of the letter, any non-selected Vendor may submit a written request for a Debriefing within the timeframe specified in the letter. A request for a Debriefing may, in the Department's sole discretion, be denied if the request is not received within the specified timeframe.

14.1.2 The purpose of the Debriefing is to compare the requesting Vendor's Response to the Solicitation document with the review document. The requesting Vendor shall be debriefed only on its Response. Because Work Order negotiations will not yet have been completed, Responses from other Vendors shall not be discussed, although the Department may inform the requesting Vendor of its relative ranking.

14.1.3 During or following the Debriefing, the Department will instruct the requesting Vendor of the manner and timeframe in which the requesting Vendor must notify the Department of its intent to request an Appeal (see Section 14.2 below), if the requesting Vendor is not satisfied with the results of the Debriefing.

14.2 Appeal Process

The Department will consider any appeal regarding Vendors not recommended for award of a Work Order under this RFS, if such appeal is received in writing by the DHS Contracts and Grants Division by the date specified in the non-selected letter. An appeal may, in DHS' sole discretion be denied if the request does not satisfy all of the following criteria.

14.2.1 The request for an appeal is submitted timely (i.e., by the date and time specified by DHS);

14.2.2 The person or entity appealing asserts, in appropriate detail with factual reasons, one or more of the following grounds for review:

A. DHS materially failed to follow procedures specified in its RFS. This includes:

1. Failure to correctly apply the standards for reviewing the Response format requirements.

2. Failure to correctly apply the standards and/or follow the prescribed methods, for reviewing the Responses as specified in the RFS.
 3. Use of review and selection criteria that was different from the criteria disclosed in the RFS.
- B. A member of the Review Committee demonstrated bias in the conduct of the review.
- C. Another basis for review as provided by State or Federal law.

Vendors will be notified by the DHS Director, or authorized designee, of the decision on any appeal which is received by DHS in a timely manner. Such notification will explain the basis for the decision. The DHS Director's decision on any appeal will be final.

15.0 WORK ORDER AWARD

A Work Order will be executed with the selected Vendor as authorized under delegated authority by the County's Board of Supervisors. The Statement of Work to the Work Order shall be agreed upon by the selected Vendor and the County, based on the Vendor's response.

16.0 NOTICE TO VENDORS REGARDING THE PUBLIC RECORDS ACT

- 16.1** Responses to this solicitation shall become the exclusive property of the County.
- 16.2** Exceptions to disclosure are those parts or portions of all Vendors that are justifiably defined as business or trade secrets, and plainly marked by the Vendor as "Trade Secret", "Confidential," or "Proprietary."
- 16.3** The County shall not, in any way, be liable or responsible for the disclosure of any such record or any parts thereof, if disclosure is required or permitted under the California Public Records Act or otherwise by law. **A blanket statement of confidentiality or the marking of each page of the Response as confidential shall not be deemed sufficient notice of exception. The Vendors must specifically label only those provisions of their respective Response which are "Trade Secrets," "Confidential," or "Proprietary" in nature.**
- 16.4** In the event the County is required to defend an action on a Public Records Act request for any of the aforementioned documents, information, books, records, and/or contents of a Response marked "confidential," "trade secrets," or "proprietary," Vendor agrees to defend and indemnify County

from all costs and expenses, including reasonable attorneys' fees, incurred in connection with any action, proceedings, or liability arising in connection with the Public Records Act request.

17.0 COUNTY RIGHTS AND RESPONSIBILITIES

The County has the right to amend, re-issue, or cancel this RFS by written addendum. The County is responsible only for that which is expressly stated in this solicitation document and any authorized written addenda thereto. Such addendum shall be made available in the DHS Contracts and Grants Portal at <http://cg.dhs.lacounty.gov/>. Should such addendum require additional information not previously requested, failure to address the requirements of such addendum may result in the Response not being considered, as determined in the sole discretion of the County. The County is not responsible for and shall not be bound by any representations otherwise made by any individual acting or purporting to act on its behalf. The County shall not be liable for any costs or expenses incurred by the Vendor in connection with the preparation and submission of any Response, nor any costs or expenses that may arise as a result of an amendment, re-issuance, or cancellation of this RFS. The County reserves the right to waive inconsequential disparities in a submitted Response.