



U N I V E R S I T Y O F
SOUTH CAROLINA

AMENDMENT NO. 1

TO: ALL OFFERORS

FROM: Damon Hightower

**SUBJECT: USC-RFP-1653-DH
Furnish, Training and Installation of IACUC & IBC Electronic Protocol
Management System Software**

DATE: April 7, 2010

This Amendment No. 1 modifies the Request for Proposals (RFP) only in the manner and to the extent as stated herein.

ITEM ONE: QUESTIONS RECEIVED WERE CONSIDERED BY THE UNIVERSITY. A DECISION WAS MADE TO ANSWER THE QUESTIONS BASED UPON THEIR VALUE TO THE SUCCESS OF THE SOLICITATION. SEE PAGE TWO FOR QUESTIONS AND ANSWERS.

BIDDER SHALL ACKNOWLEDGE RECEIPT OF AMENDMENT NO. 1 IN THE SPACE PROVIDED BELOW AND RETURN IT **WITH THEIR PROPOSALS**. FAILURE TO DO SO MAY SUBJECT BID TO REJECTION.

Authorized Signature

Firm

Date

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ITEM ONE:

THE FOLLOWING QUESTIONS WERE RECEIVED FROM VENDORS:

- Question #1** Would you consider an alternative state wide solution for HSSC, or is the desire to have a dedicated local system at USC?
- Answer #1** The desire is to have a dedicated local system.
- Question #2** The RFP states that support for Oracle 10.2 or 11g is required. Does this imply that the desired solution must run on top of Oracle, or that the solution must be able to interface with other Oracle databases at the institution? The Click Commerce solution is built on a Microsoft SQL Server database, but we regularly interface to other applications (such as PeopleSoft, Banner, etc.) which are running on Oracle.
- Answer #2** The database needs to run on top of Oracle
- Question #3** Please define the desired functionality for “Veterinary management” listed under required product features.
- Answer #3** Animal ordering (submission, review and approval)/order accounting, cage cards production/management, training records management, animal transfers, billing (including per diems), and animal census tracking must be possible with software. Reports of any data required or requested by regulatory agencies, including, but not limited to, the USDA and AAALAC, Int., should be easily produced by software.
- Question #4** Number of active studies?
- Answer #4** Currently about 200, but software should not in any way limit maximum number of active studies.
- Question #5** Number and type (i.e., Exempt, Expedited, Full Board) of Studies submitted per year?
- Answer #5** Approximately 150, but software should not in any way limit maximum number of submissions
- Question #6** Number of PIs and Researchers?
- Answer #6** Approximately 100, but software should not in any way limit maximum number of PIs and Researchers
- Question #7** Number of compliance administrators/analysts
- Answer #7** 1, but software should not in any way limit number of personnel
- Question #8** Number of Review Boards?
- Answer #8** 1 IACUC

Question #9 Number of physical sites?

Answer #9 3-4 animal facilities, but software should not in any way limit number of physical sites

Question #10 What are the ancillary (non-blocking) review requirements (e.g., Radiation Safety, BioSafety, Conflict of Interest, Scientific Review Committee, and GCRC)?

Answer #10 Radiation Safety, Biosafety

Question #11 What are the department and organizational review requirements for Amendments, Continuing Reviews, and Reportable Events (e.g., Adverse Events and Protocol Deviations)?

Answer #11 As required by regulations and guidelines for compliance. Amendments, Continuing Reviews, and Reportable Events are reviewed by the IACUC. Department chair approval of application.

Question #12 Describe the Designated Member Review process?

Answer #12 If minor revision of an AUP is required, a designated reviewer (DR) may be assigned by the IACUC. The DR has the ability to approve the revised AUP, require additional revisions, or send the revised AUP to the IACUC for full committee review.

Question #13 What are the facilities management, materials tracking and inspection requirements?

Answer #13 Animal ordering (submission, review and approval)/order accounting, cage cards production/management, training records management, animal transfers, billing (including per diems), and animal census tracking must be possible with software. Reports of any data required or requested by regulatory agencies, including, but not limited to, the USDA and AAALAC, Int., should be easily produced by software.

Question #14 Number of active IBC protocols?

Answer #14 100

Question #15 Number of new submissions per year?

Answer #15 25-50

Question #16 Do you have an existing electronic system? Is so, will need screen shots of major forms and sample reports.

Answer #16 No

Question #17 Number of compliance administrators/analysts?

Answer #17 1

Question #18 Number of Review Boards?

Answer #18 1

Question #19 Number of physical sites?

Answer #19 75 labs and facilities

Question #20 What are the ancillary (non-blocking) review requirements?

Answer #20 IACUC

Question #21 What are the department and organizational review requirements

Answer #21 Department level approval.

Question #22 What are the annual review and amendment workflow requirements?

Answer #22 The same new projects (similar to IACUC).

Question #23 Is this site to be added to an existing Click Application (e.g., IRB or Grants)?

Answer #23 This is possible, but not essential or preferred.

Question #24 What is Customer's development approach? [Click does it all, Customer does most, blend]

Answer #24 Blend

Question #25 What is the makeup and experience of Customer's development staff?

Answer #25 The development staff will involve administrators from the IACUC and IBC with support from IT as necessary.

Question #26 Customer Project Manager: does customer have one and what is experience level?

Answer #26 There likely will not be an experienced project manager and much will be done "by committee".

Question #27 What the anticipated project start date?

Answer #27 June 1, 2010.

Question #28 Is single sign on (SSO) or central account authentication (e.g., LDAP) required? If so will this be the first application?

Answer #28 Not required at this time, but institutional protocol is under review and may become required.

Question #29 Internet access required or will the system be behind the firewall and require external VPN access?

Answer #29 Internet access required

Question #30 Single server or split configuration?

Answer #30 Probably single server.

Question #31 What are the external interfaces (e.g., Personnel, Accounting, Animal Operations, Adverse Events, Clinical Trials, Electronic Medical Record (EMR), Patient Scheduling, and Charge Master)? Describe data and frequency of exchange. Also, will they need Web Services?

Answer #31 None planned at this time, possibly linked to internal grants management system which is a “homegrown” solution.

Question #32 Data conversion: how much and type data (e.g., protocols and personnel) is expected to be moved into the site?

Answer #32 Data likely will be entered into the new system at the time of continuing review, annual review, and new application. Don’t anticipate large data transfer.

Question #33 What are the high-level reporting requirements? Currently using a reporting database?

Answer #33 Currently using Access database or similar.

Question #34 If you don’t want us to submit our standard software license agreement terms as a part of the RFP, how do you suggest we communicate that information?

Answer #34 Offeror may submit any proposed agreement that the University is to consider during negotiations in its proposal.

NOTE: All proposed agreements submitted should include an appropriate disclaimer (i.e. the proposed agreement(s) is only included with this proposal as a sample. If the University can consider the contents of the sample proposed agreement(s) for inclusion in the negotiations of a potential contract with our company, that would be appreciated. Otherwise, it is not intended for the University to consider this sample proposed agreement(s) in its evaluation of our company’s proposal). Submitting proposed agreements without including an appropriate disclaimer can sometimes result in an offeror’s proposal being deemed “non responsive” and removed from further consideration.