

**Questions Pertaining To Section 2.0: Eligibility and Partnering**

**1. Can the proposal have co-Principal Investigators?**

As outlined in Section 9.0 of the RFP there must be a prime CTSA institution with a single corresponding point of contact that is solely, and contractually responsible for the execution of the project and coordination with the other listed partners on the project. Equally, there must be a single Principal Investigator designated as responsible for the overall project; Co-Investigators under this single responsible lead may be proposed.

**2. Can one of the co-PIs be from a non-CTSA institution?**

Co-Investigators may be from any partner institutions.

**3. Is a CTSA awardee institution permitted to participate in more than one proposal under this RFP?**

Yes, a CTSA awardee institution is permitted to participate in more than one proposal in response to this RFP.

**4. Is a single CTSA (as the lead site) limited to one application? Or could one CTSA site put in two proposals if there were distinct informatics development programs planned, and separate PI's?**

See answer to question 3 above.

**5. Is one CTSA allowed to submit more than 1 proposal as a lead?**

See answer to question 3 above.

**6. Is there any restriction on the number of proposals each institution may participate in, either as lead or as a subcontract for RFP 08-001?**

No. There is no restriction on the number of proposals each institute may participate in.

**7. Is there any conflict in an institution submitting multiple (presumably separate research area) response to the RFA?**

No. There is no restriction on the number of proposals each institute may submit.

**8. Are foreign institutions allowed as a subcontractor?**

The use of foreign institutions or companies is allowable. However, the foreign subcontractor must be pre-approved by Booz Allen Hamilton. Additionally, the lead CTSA and their subcontractor(s) would be subject to the following FAR clause.

**52.225-13 -- Restrictions on Certain Foreign Purchases.**

As prescribed in 25.1103(a), insert the following clause:

**Restriction on Certain Foreign Purchases (Feb 2006)**

- (a) Except as authorized by the Office of Foreign Assets Control (OFAC) in the Department of the Treasury, the Contractor shall not acquire, for use in the performance of this contract, any supplies or services if any proclamation, Executive order, or statute administered by OFAC, or if OFAC's implementing regulations at 31 CFR chapter V, would prohibit such a transaction by a person subject to the jurisdiction of the United States.
- (b) Except as authorized by OFAC, most transactions involving Cuba, Iran, and Sudan are prohibited, as are most imports from North Korea, into the United States or its outlying areas. Lists of entities and individuals subject to economic sanctions are included in OFAC's List of Specially Designated Nationals and Blocked Persons at <http://www.treas.gov/offices/enforcement/ofac/sdn/>. More information about these restrictions, as well as updates, is available in the OFAC's regulations at 31 CFR chapter V and/or on OFAC's website at <http://www.treas.gov/offices/enforcement/ofac>.
- (c) The Contractor shall insert this clause, including this paragraph (c), in all subcontracts.

(End of clause)

**Questions Pertaining To Section 3.0 Letter of Intent**

**9. Is there a suggested format for submitting a LOI for this RFA?**

The Letter of Intent (LOI) requires no specific format and should be e-mailed to [ctsa\\_solicitations@bah.com](mailto:ctsa_solicitations@bah.com) by February 25, 2008, 5:00 PM EST.

**Questions Pertaining To General Submission**

**10. March 10th is quite a ways away, and a very significant amount of work would rest on your answer to the question we posed. Could we perhaps get a tentative answer this week?**

We are responding to initial questions with this posting and may post additional responses prior to March 10, 2008. All questions must be received by February 25, 2008, 5:00 PM EST and will be responded to by March 10, 2008.

**11. Also, do these proposals need to have faculty PIs, or can someone with a professional position be a PI (e.g. myself – not that I'm the one considering applying this time around)**

There are no faculty requirements of the RFP for the Principal Investigator responsible for the overall project. Submitting institutions may have requirements on who can serve as the PI for a submission from that institution. We expect the responding institution to select the person most appropriate and qualified to fulfill the PI role. The PIs qualifications must be outlined in the proposal and attached resume or biosketch, which will be reviewed by the evaluation panel.

**12. Will the applications which are funded from the RFP 08-001 be awarded from NCRR or as a subcontract from Booz Allen?**

The applications will be funded as a subcontract from Booz Allen.

### **Questions Pertaining To Project Details**

**13. A question has come up about the recent RFA for CTSA informatics pilot projects. At first glance, it might be interpreted to be focusing solely on clinical research data management systems (that collect the primary patient data for trials and other studies). My impression is that the RFA's focus includes such systems, but also includes any databases and systems that would support a variety of different aspects of conducting clinical research. Thus a system like caTISSUE, for example, which focuses primarily on managing information related to specimens used in clinical & translational research, would be a perfectly appropriate for the RFA. Is this broader interpretation correct?**

The focus of the current RFP is specifically on “the implementation, adaptation, development, and application of tools for clinical investigators and their research team to facilitate the performance of small and medium sized research studies, specifically related to the collection, management, and security of human subjects study data.”

The goal of this solicitation is to provide clinical investigators and clinical research teams at and across CTSA institutions informatics tools to enhance the collection and management of data in small and medium sized single and multi-site studies while ensuring the accuracy, quality, confidentiality, and security of the data.

All responsive proposals must clearly address these goals.