

Additional Business Proposal Instructions

In addition to instructions and format requirements for the Business Proposal that are contained in the solicitation, the information presented in this attachment is intended to provide uniform cost assumptions that apply to the solicitation.

Offerors are advised to give careful consideration to the Statement of Work, all reference material provided as attachments, the technical evaluation criteria, and the RFP as a whole, in the development of their proposal. The information provided here shall be used as further guidance for the development of the Business Proposal.

For proposal purposes, offerors shall propose based on the following budget assumptions:

1. Anticipated core staffing hours of 8:30 AM ET-5:00 PM ET, Monday-Friday. No staffing is required on Federal Holidays
2. All computers, phones, office supplies/equipment, voicemail, email, and conference call accounts will be provided by the Government.
3. Offerors should use the estimate that the PIO will handle approximately 2,000 protocol-related documents per year, which includes: Project Team Applications, Letters of Intent, Concepts, Protocols, Revisions, Amendments, IRB approvals.
4. The Contractor should estimate that it will require approximately two (2) hours to completely abstract a Protocol and approximately one (1) hour to completely abstract an LOI, PTMA, Concept, Revision and Amendment. This time includes data element abstraction, file preparation, processing comments and inquiries, and distribution of related correspondence.
5. Appendix 2 of the Statement of Work contains a table with breakdown in volume by document type. In 2014, the incumbent Contractor distributed approximately 272 special mailings to investigators related to adverse events affecting approximately 4,100 protocols. The Contractor's effort per mailing is approximately one (1) hour. If a mailing results in an amendment to a protocol, the approximate additional time stated above is required to process the amendment.
6. In 2014, the incumbent Contractor fulfilled approximately 107 typing requests made by CTEP personnel (typically, represents a request made by a lead reviewer to modify documentation that will be distributed to the submitter), requiring an average of 45 minutes per request.
7. The Contractor shall prepare packets for weekly IDB, CRM, BRC and PRC meetings. It takes approximately one (1) hour weekly to prepare the IDB, BRC and CRM meeting packets and approximately two (2) hours to prepare the PRC meeting packet.
8. The Contractor shall orient new staff to CTEP. Orientation lass approximately one (1) hour. In 2014, the incumbent Contractor conducted approximately ten (10) such orientations.
9. The contractor shall support the Operational Efficiency Working Group initiative. In 2014, the contract staff handling this task set up 200 conference calls which lasted 30 minutes per

call on average, one hour to write up, circulate for internal review and distribute minutes to the protocol team

- 10.** The cost for the phase-out transition shall be provided as a separate budget as well as a category in the total estimated budget.
- 11.** The Contractor shall conduct a minimum of four (4) training programs annually. The programs are developed by CTEP and will be at least one (1) hour in length and can occur in person, be web-based or conducted via a video conference. The programs shall be delivered to CTEP personnel, CTEP contractors or submitters and submitter personnel who interact with CTEP, as directed by the COR. The training programs shall serve as orientation of new personnel (i.e., CTEP personnel, CTEP contractors or submitters, and submitter personnel who interact with CTEP), training of new processes, or updates on existing processes.
- 12. Options:**
 - **Increased Capacity:** Assume an increase of 20% of base work costs per year through increased capacity options. Please include increased capacity option costs for each year as part of the proposed budget.