

Attachment #6: Additional Business Proposal Instructions

In addition to the instructions and format requirements for the Business Proposal that are contained in Section L of 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 your proposal. The information requested here shall be used as further guidance for the development of your Business Proposal. For proposal purposes, the offeror shall propose based on the following budget assumptions (Note: all workload assumptions are approximations):

1. Manage and Support all CIRB's

- A. Adult CIRB – Late Phase Emphasis – meets twice per month.
- B. Adult CIRB – Early Phase Emphasis – meets twice per month.
- C. Pediatric CIRB – meets monthly.
- D. DCP CIRB (to be established) – meets monthly.
- E. Separately propose an additional CIRB if needed – meets monthly.
- F. Unless otherwise specified, all meetings will be conducted via teleconference.
- G. Each CIRB has three Subcommittees:
 - 1. Conflict of Interest Subcommittee – meets on an ad-hoc basis typically twice a year when it is unclear if a member has a conflict of interest.
 - 2. Adverse Event Subcommittee – meets on an ad-hoc basis, typically twice a year to review adverse event reports when a CIRB-approved study does not have a monitoring body or DSMB reviewing those reports.
 - 3. Local Context Subcommittee – On an ongoing basis members review local context and new study Worksheets submitted by institution staff and institution principal investigators; members also review any submissions from institutions, e.g., reports of potential unanticipated problems or noncompliance, locally developed educational/informative study-specific materials targeted to potential or active study participants. The committee reviews approximately 500 documents per month.
- H. The Adult CIRB – Early Phase Emphasis is expected to review at least 40 new studies per year.

- I. The Adult CIRB – Late Phase Emphasis is expected to review at least 25 new studies per year.
- J. The Pediatric CIRB is expected to review at least 25 new studies per year.
- K. The 4th CIRB to review DCP trials is expected to review at least 12 new studies in the first year and at least 24 new studies per year after the first year.
- L. Currently there are approximately 140 studies on the Adult CIRB - Late Phase Emphasis menu.
- M. Currently there are approximately 106 studies on the Pediatric CIRB menu.
- N. Each CIRB has approximately 16 members (one chair; one vice-chair; and 14 members). Members receive \$400 honorarium for each meeting attended, Chairs receive \$1,000, and Vice Chairs receive \$700 per meeting. These costs will be reimbursed by this contract. This should be proposed as a uniform cost assumption.
- O. Service on the NCI CIRB is outside the scope of the member's employment; therefore liability insurance coverage is needed if an individual wants to serve on any particular CIRB. The CIRB contractor shall provide liability insurance for all CIRB participants.
- P. Please use the spreadsheet provided in the RFP for all costs submitted.

2. Manage and Support New and Already Enrolled institutions

- A. The Contractor shall post all study-related documents and correspondence associated with a CIRB review to the CIRB area of the CTSU website. Local institution staff can access the website to obtain the documents. For the past 12 months, the monthly median of the number of documents posted to the website is 461. The public side of the website is located at the following URL www.ncicirb.org.
- B. The institution's primary contact submits an Annual Institution Worksheet about Local Context and the institution Principal Investigator submits an Annual Principal Worksheet about Local Context to inform the CIRB about local context considerations. There are approximately 109 Institution Worksheets and 449 PI Worksheets submitted to date.
- C. The institution's Principal Investigator submits a Study-Specific Worksheet to open a new study. There have been approximately 354 Study-Specific Worksheets approved by the CIRBs to date.

- D. There will be approximately 750 local institutions enrolled in the CIRB Initiative when the contract begins. The remaining approximately 500 institutions conducting NCI-sponsored trials are expected to enroll within the first two contract years of contract award.
- E. The helpdesk is experiencing a current volume of approximately 330 queries a month.

3. **Travel**

- A. Assume six trips will be taken for two CIRB operation staff members each year. Three (3) trips to the east coast and three (3) trips to the west coast. Each trip will be approximately 2 days in length. This should be proposed as a uniform cost assumption.
- B. Assume one trip to NCI for the transition initiation meeting.
- C. There are an average of five conferences (e.g., PRIMR, AAHRPP, and Cooperative Group meetings) a year, which Contractor staff will be expected to attend to set up and staff the information/outreach booth. Staff members will give the presentation about the CIRB. For cost estimating purposes, three meetings could be located in the Chicago area and two could be located in the San Diego area.

4. **IT Support**

- A. IRB Manager – The NCI has a license, including hosting and maintenance of both a testing and production server environment for IRB Manager©. For the first 18 months of the period of performance, the contractor shall pay for the IRBManager© license with contract funds. The annual license fee is approximately \$110,000. In addition the Contractor shall provide annual custom configuration maintenance, development, and web-services linking IRB Manager to other NCI IT systems that shall be transferred from the incumbent to the successful awardee.
- B. CIRB Public and Member's Website – All content, source code and web-services to other NCI IT systems shall be transferred from the incumbent to the successful awardee. The contractor shall provide website hosting for the CIRB public website.
- C. CIRB institution enrollment data – The incumbent contractor utilizes a proprietary IT system called Advantage EDCSM (<https://secure.emmes.com/emmesweb/products/advantage>), to collect, track and maintain institutional CIRB participation and enrollment data. To facilitate a smooth transition the contractor shall procure a license for the first 18 months of the period of

performance, including hosting and maintenance for AdvantageEDC. The approximate annual license fee is \$75,000. In addition the Contractor shall provide annual custom configuration maintenance, development, and web-services linking Advantage EDC to other NCI IT systems that shall be transferred from the incumbent to the successful awardee.

- D. CIRB Board Member Tracking – All CIRB Board member data including but not limited to Name; contact information; deposit information; board participation, training, assignment completion, attendance, and role or area of expertise shall be transferred from the incumbent to the successful awardee. This incumbent utilizes an MS Access data base. The successful awardee shall include a plan for long term management of CIRB Board Member tracking, including a web-based interface for current board members to update information; as well plan for long term storage and maintenance of CIRB board member data.
- E. ePanel® (<https://www.epanel3.com/>)– ePanel® is a document review, collaboration, and meeting support tool that is currently utilized by the CIRB. ePanel® will be procured by the NCI and provided to the successful awardee for the first 18 months of the contract award. The Contractor shall provide a document review, collaboration, and meeting support solution for the remainder of the period of performance that shall be transferred from the incumbent to the successful awardee.