*Awarded for CoAg no. 5U01GH000152-05: New Money*

**Project Name: TB-EnTIC-BTB**

**Appendix B: (Contractual)**

Required Information for Contract Approval

**All contracts require prior approval from CDC/Atlanta. Funds may not be used until the following required information for each contract is submitted to and approved by CDC/Atlanta:**

1. **Name of Contractor:** Mahidol University
2. **Method of Selection:** Sole source contract. The contract is third year continuation of previously established and PGO-approved contract. Selected service provider is Mahidol University.

**Justification for renewing the contract**

**Project requirements to service provider:**

EnTIC Study primary outcome data collection at study months 0, 12 and 24 requires:

* knowledge and understanding of the 173-page scientific protocol, including 12 data collection tools
* skills and knowledge of handling specialized laboratory equipment and custom electronic software systems developed specifically for the study
* skills and knowledge of handling confidential study documents (i.e. informed consent, healthcare worker demographics)
* sensitivity, knowledge and understanding of human subjects ethical standards and practice procedures to protect individual and institutional study participants at 10 participating hospitals
* established relationships with hospitals’ administrators in supporting safety culture survey administration and hospital infection control study points-of-contacts
* agreement to protect study documents and study data

EnTIC secondary outcomes data collection at study months 0, 6, 12, 18 and 24 requires:

* knowledge and understanding of the study protocol, including study secondary data collection forms and tools
* knowledge of tuberculosis transmission and infection control practices selected specifically for the study
* understanding and practice staying safe from TB and other infections while working in 10 hospitals
* experience in extracting specific data from hospital information systems and individual patient charts per requirements of the study protocol
* sensitivity and knowledge of hospital-specific tuberculosis infection control audits/observations at each of the ten hospitals participating in the project

**Unique qualifications of the selected service provider:**

The Mahidol University Research Team underwent comprehensive 4-days of study specific training in study protocol and study procedures (see requirements above) before the study start in 2013 and 3 days of training since the study start. The training was provided by the CDC and the BTB staff. Study-specific training included:

* coordinate data collection dates and schedules to assure study timelines are met
* prepare sites for data collection
* recruit healthcare workers
* practice safety precautions in hospitals
* record and manage study-specific adverse events
* observe and document healthcare worker and patient interactions
* trouble-shoot potential challenges (i.e. patient volumes/flows, structural features of facilities, days and hours of operation, work schedules)
* awareness of methodological considerations (i.e. the Hawthorne effect, inter-rater reliability, observer bias)
* follow study-specific standard operating procedures to collect and report data

The Mahidol University Research Team successfully completed a) primary endpoint data collection at baseline and year one evaluations and b) secondary endpoints data collection at baseline evaluation, therefore the team possesses not only specialized knowledge based on trainings, but also practical experience.

1. **Period of Performance:** September 1, 2015– August 31, 2016

**Scope of Work:**

The contractor will be responsible for the following aspects of study implementation:

* Hiring and training of study staff
* Liaison with 10 participating hospitals and financial management of hospital staff overtime
* Participate investigator meetings
* Arranging for all needed staff and site training, according to agreed study plan
* Manage preparations for field data collection teams for the primary outcome (IGRA) at each hospital site, including travel logistics
* Conduct all secondary data collection at each participating hospital site according to the timeline (study months 12, 18, and 24) and using the tools in the study protocol
* Data transfer to BTB and TUC for data entry
* Management of study files according to agreed plan
* Participation in data analysis, interpretation, and manuscript development

In the first budget period, we expect the following deliverables:

1. Hiring and training of study staff
2. Review and revision of detailed SOPs
3. Biweekly progress updates to collaborators
4. Prepare work plan and schedule with hospitals and team for conduct secondary outcome data collection
5. **Method of Accountability:**

Dr.Chawetsan Namwat, the Director of TB Bureau, the Thailand Ministry of Health, will be responsible for monitoring the progress of the project. He directly oversees Thailand’s National TB Program in Thailand and will provide oversight for contractor.

1. **Itemized Budget and Justification:**

Itemized budget is calculated to be minimally adequate for the contractual to accomplish the tasks listed above.

**Total Cost: $177,419.35 (New Money Approved $39,478.42)**

Please see attached for budget details.