January 17, 2019

ADDENDUM NO. 1

RFP 191904
Consulting Services for Establishing a Clinical Trial Program Site

1. Note additional or revised language inserted into this section:

SECTION II – PURPOSE OF THE RFP

1. INTENT

As part of that transformational agenda to benefit society, ASU is exploring engaging in clinical trials and clinical research. ASU proposes to develop a model for community-based research, rather than a typical program based in tertiary care facilities. **ASU envisions a model including, for example, physician practice groups, outpatient surgical centers, telemedicine providers, physical & occupational therapists, and integrated care providers as well as hospitals and research institutions.** Such programs match the missions for the College for Health Solutions (CHS) as it works to transform society's focus from illness to health, the Biodesign Institute, with its premise that scientists can overcome complex societal issues by re-imagining nature’s “design rules,” and the College of Nursing & Health Innovation’s nationally recognized academic program that prepares clinical research managers. Performing clinical trials represents a novel arena for ASU, which does not have its own medical school. Therefore, establishing this capability will require investment into infrastructure and personnel required for this activity. Once established, this capability will position ASU to **contribute to community health, provide learning and research opportunities, and** compete for various grants and contracts that it cannot compete for now. ASU is seeking a consultant to evaluate the **potential of this community based model** and help assess the costs, risks, and benefits of pursuing this strategy. We are anticipating an initial three (3) to six (6) month consulting project.

The product for the study will be a report detailing the potential size of the research opportunity for this regional market, an evaluation of ASU’s current capabilities in the program area, information about competitors, and the size of any investment required for ASU to become both compliant and competitive in that arena. This will provide ASU with the information it needs to assess whether it should embark on this endeavor. **Consultant will work directly with the Dean of the College for Health Solutions, and the Director of the BioDesign Institute or their designees, on this project.**

2. Note additional or revised language inserted into this section:

SECTION V – SPECIFICATIONS/SCOPE OF WORK

Proposers to provide a Clinical Trial Program Site report detailing the potential size of the research opportunity for this regional market, an evaluation of ASU’s current capabilities in the program area, information about competitors, and the size of any investment required for ASU to become both compliant and competitive in that arena.
The following is a list of some critical questions that need to be addressed in Proposer’s detailed written response:

1. What is the size of the market for community-based clinical trials in Arizona? Are there specific subsets of the overall clinical trial market for which Arizona is particularly well suited?
2. Who are our potential customers, competitors, and partners?
3. What are ASU’s current strengths that could be applied to clinical trials? Which areas need strengthening?
4. What new resources and expertise would be required to be successful in this endeavor?
5. What financial investment and timeline would be required to build needed capabilities?
6. Are there specific infrastructure needs for this program?
7. What are the key and significant opportunities and threats?
   a. Can they negatively impact the reputation/image of ASU?
   b. Define legal risks, if any, which might arise?
   c. Are there possible negative impacts on existing relationships, programs and projects at ASU?
8. Could such a program become financially self-sufficient? How?
9. How and when could we expect to recover ASU’s investments in the program?

Proposers to include all information necessary in order for ASU to make an informed decision on whether or not to move forward with establishing their own Clinical Trial Program Site.

Value Added Services

1. Proposer should provide a brief summary of any other value-added services or programs which may contribute to the overall value of your proposal, including but not limited to:
   a. Training
   b. Industry Partnerships
   c. Support of ASU’s Charter and Goals
   d. Support of sustainable development, veterans’ affairs, initiatives in support of women, wellness, and our changing regional demographics
   e. Support and enhancement of ASU’s reputation as an innovative foundational model for the New American University
   f. Comment to provide significant financial and non-financial support for the University and its signature program

Please remember that Proposals are to be mailed or delivered to Arizona State University, Purchasing and Business Services, 1551 S. Rural Rd. Tempe, AZ 85281, no later than 3:00 P.M., MST, 02/08/19.

Questions regarding this notice, please contact me at 480-965-3270 or karen.ashe@asu.edu. All postings for RFP 191904 can be found at http://www.asu.edu/purchasing/bids/index.html.

Thank you,

Karen S. Ashe

Karen S. Ashe, Purchasing Manager
Purchasing and Business Services