United States Small Business Administration
Office of Hearings and Appeals

NAICS APPEAL OF:	
Information Ventures, Inc.	SBA No. NAICS-4882
Appellant	Decided: January 18, 2008
Solicitation No. NHLBI-DE-08-16 National Heart, Lung and Blood Institute National Institutes of Health Bethesda, MD	

APPEARANCES

Bruce H. Kleinstein, Ph.D., J.D., President, Information Ventures, Inc., for Appellant

Rick Phillips, Contracting Officer, for the National Heart, Lung and Blood Institute, National Institutes of Health

Anna B. Slavin, Vice President, for New England Research Institutes, Inc.

DECISION

HOLLEMAN, Administrative Judge:

I. Jurisdiction

This appeal is decided under the Small Business Act of 1958, 15 U.S.C. § 631 *et seq.*, and 13 C.F.R. Parts 121 and 134.

II. Issue

Whether the appropriate NAICS code for clinical research operations and management support is 541712, Research and Development in the Physical, Engineering, and Life Sciences (except Biotechnology), or 541690, Other Scientific and Technical Consulting Services.

III. Background

A. The Solicitation

On December 3, 2007, the National Institutes of Health, National Heart, Lung and Blood Institute, in Bethesda, Maryland (NHLB), issued the subject solicitation for clinical research operations and management support for the National Institute of Dental and Craniofacial Research (NIDCR). The Contracting Officer (CO) set the procurement totally aside for small businesses, and designated North American Industry Classification System (NAICS) code 541712, Research and Development in the Physical, Engineering, and Life Sciences (except Biotechnology), with a corresponding 500 employee size standard, as the NAICS code for this procurement. Proposals are due on February 8, 2008.

B. Statement of Work

The purpose of this requirement is to provide comprehensive clinical research operations support, management and data coordinating services for NIDCR's clinical studies. The contractor will provide NIDCR with clinical research management support and oversight tools to assist in the effective administration and coordination of its clinical research program. The contractor is also to provide expertise and resources to assure sound and efficient clinical study design, study execution, data management and analysis, and regulatory compliance.

The Statement of Work (SOW) identifies twelve tasks, each with subtasks:

Task 1. Study Design, Protocol Development and Study Documents/Materials Preparation

The contractor shall consult with NIDCR staff on study concept development, clinical study design and study protocol development; assist NIDCR staff in feasibility assessments of concept proposals; work with NIDCR staff in devising sound and mutually acceptable protocols and study documents; develop and use NIDCR-approved standardized protocol and associated document templates; and establish and implement a system to ensure appropriate version control, storage and management of study documents.

Task 2. Clinical Site Preparation and Clinical Research Operational Assistance

The contractor shall provide clinical research management and support services to NIDCR clinical research sites during all phases of research from study preparation and initiation through study completion and close-out. Subtasks include conducting site operational assessment visits; working to resolve any noted site deficiencies; designing, preparing, and distributing site preparation aids; providing general management and operational support to study personnel; assisting clinical sites in the establishment of quality management (QM) programs that include quality control (QC) and quality assurance (QA), preparing standard operating procedures (SOPs) and assisting in the review and resolution of issues identified in site assessment reports.

Task 3. Data Collection, Management and Quality Control

The contractor shall establish, operate and maintain a state-of-the-art computer based-system for the collection, management, storage and quality control of all clinical and laboratory research data and for the management and reporting of data for NIDCR's clinical trials and studies.

Task 4. Training and Training-Related Activities

The contractor shall provide clinical research-related training to NIDCR staff and study site personnel as required to facilitate sound protocol conduct and clinical research management.

Task 5. Regulatory Submission Support and FDA Interface Coordination

The contractor shall provide technical and administrative support to NIDCR staff in preparation and submission of documents to the Food and Drug Administration (FDA) and assist NIDCR staff in dealing with the FDA.

Task 6. Specialized Operational Support

The contractor will provide certain support activities when required by the Project Officer, such as specimen storage, product distribution, and preclinical product testing.

Task 7. External Quality Assurance Clinical Site Monitoring

The contractor shall provide external QA monitoring support for NIDCR's clinical studies. The monitors provided must be experienced, trained and have sufficient scientific and clinical background and knowledge to effectively perform their tasks.

Task 8. Pharmacovigilance/Safety Monitoring

The contractor shall design, develop, implement and maintain an Adverse Event/Serious Adverse Event (AE/SAE) reporting system that will constitute NIDCR's Pharmacovigilance Program. The system will report track and archive AE/SAEs for all NIDCR clinical studies.

Task 9. Statistical Design and Analysis and Reporting

The contractor shall provide advice and assistance in the development of appropriate statistical designs and statistical analysis plans in the preparation of interim and final analyses for clinical research studies supported by NIDCR.

Task 10. Information Management Systems

The contractor shall develop, maintain and update computer-based systems (e.g., centralized databases and websites) necessary to support the clinical research management activities outlined in the SOW.

Task 11. General, Logistical Support and Administrative Coordination

The contractor shall provide administrative support for various functions such as meeting planning, communications, study material distribution and special reports.

Task 12. Contract Transition

The contractor shall prepare and conduct a smooth transition at the contract's completion.

The evaluation factors for award require the proposal to document the training, experience, and leadership of the lead Principal Investigator with domestic and international research program management experience and regulatory expertise. The contractor must also document the expertise and experience of project/site managers and monitors. In evaluating proposed personnel, the procuring agency will emphasize management experience with clinical research and trials. Special attention will be paid on the ability to separate operational units to eliminate potential conflicts of interest, and ensure that QA monitoring remains independent from other site management activities. In the technical staff, the solicitation seeks to have documented training and experience to perform the tasks in the SOW, and expertise in similar projects.

C. The Appeal

On December 12, 2007, Information Ventures, Inc. (Appellant) filed a NAICS code appeal with the Office of Hearings and Appeals (OHA), challenging the CO's NAICS code designation. Appellant asserts that the appropriate designation is NAICS code 541690, Other Scientific and Technical Consulting Services, with a corresponding $6.5 million annual receipts size standard.

On December 13, 2007, I ordered the CO to notify any interested persons of the pendency of this appeal and to provide OHA with a list of such persons. Also on December 13, 2007, I established December 28, 2007, as the close of record in this case. At the CO's request, I later extended this deadline to January 7, 2008.

Appellant argues that the SOW does not require the contractor to engage in research and development in physical, engineering, and life sciences as required by NAICS code 541712. The principal work involves providing comprehensive clinical research operations support, management and data coordinating services for NIDCR's clinical research. These tasks are not laboratory or other physical research and development. Appellant argues that "Research and Development" means laboratory or other physical research and development. This solicitation does not seek to acquire research or experimental development in the physical, engineering, or life sciences to provide a product or service.

Appellant asserts that for a procurement to be designated under NAICS code 541712 it must include: (1) original research or the application of research for the creation of new or improved processes or products; (2) research and development in the physical sciences, engineering sciences, or life sciences; and (3) laboratory or other physical research. This

solicitation does not require any of these activities. This solicitation requires giving advice, assistance and support, it does not require either laboratory or physical research. Appellant further asserts that SBA's regulations exclude operations research, systems research, and other nonphysical research from this code, as well as computer programming and data processing, and thus exclude much of the work under the SOW in this procurement. *See* 13 C.F.R. § 121.201, n. 11. The solicitation requires that the contractor's staff have clinical research experience, but it does not require the contractor to perform research.

In support of its argument that NAICS code 541712 does not apply to the instant procurement, Appellant cites OHA's decisions in *SIC Appeal of Information Ventures, Inc.*, SBA No. SIC-4259 (1997) and *SIC Appeal of The Cadmus Group, Inc.,* SBA No. SIC -3315 (1990), where OHA concluded that Standard Industrial Classification (SIC) code 8731, the predecessor of NAICS code 541712, did not apply to the statements of work there at issue.

Appellant further argues that NAICS code 541690 is the only appropriate code. This code covers giving advice, assistance and support activities in scientific matters. These are the type of tasks the SOW requires of the contractor. Appellant further asserts that any computer-related code would be inappropriate, because the services here are not primarily computer-related.

D. Responses to the Appeal

On January 7, 2008, New England Research Institutes (NERI) filed a response to the appeal. NERI asserts that the SOW requires the contractor to develop, implement, support, manage, and analyze multiple and complex clinical research initiatives and directives, including clinical trials as well as population-based, epidemiologic, behavioral and natural history studies. These tasks clearly encompass conducting research. The SOW calls for significantly more effort than the providing of advice and assistance called for by code 541690.

On January 8, 2008, the CO submitted a response to the instant appeal. The CO argues that 541712 is the correct NAICS code for the procurement. The CO went on to discuss each of the tasks in the SOW.

Task 1. Study Design, Protocol Development and Study Documents/Materials Preparation

The work performed under this task is best characterized as primarily research and development (R&D), or is in direct support of R&D. This task requires great experience and expertise with clinical R&D. The task requires daily interactions with contractor staff and investigators. The contractor must have experience in medicine, epidemiology, biostatistics, human subjects protections, FDA regulations, laboratory services for clinical trials, clinical research conduct and subject safety oversight.

Task 2. Clinical Site Preparation and Clinical Research Operational Assistance

The work performed under this task is best characterized as primarily R&D, or in direct support of R&D. It requires expertise and experience with clinical R&D, and the design and

conduct of clinical research and trials. The site assessment is crucial to the success of a clinical trial. The contractor not only makes the clinical site assessment, but follows up with the implementation of solutions in order to optimize a successful outcome.

Task 3. Data Collection, Management and Quality Control

This task is primarily for data and information management services, but requires specialized clinical, medical, scientific, and technical expertise to perform properly.

Task 4. Training and Training-Related Activities

The CO estimates that this task is best characterized as 40% R&D, or in direct support of R&D. While some of the subtasks here are purely administrative, scientific and technical consulting services is appropriate for assessing training needs and evaluating training programs.

Task 5. Regulatory Submission Support and FDA Interface Coordination

The CO assets this task is predominately R&D or in support of R&D. The task requires medical and clinical expertise, as well as regulatory experience.

Task 6. Specialized Operational Support

The CO assets this task is predominately R&D or in support of R&D. These tasks are in direct support of clinical trials, and underpin all clinical product development.

Task 7. External Quality Assurance Clinical Site Monitoring

The CO assets this task is predominately R&D or in support of R&D. This requires a clinically trained staff with research and trial experience and knowledge of Federal regulations and international guidance.

Task 8. Pharmacovigilance/Safety Monitoring

The CO assets this task is predominately R&D or in support of R&D. This task requires specialized expertise and experience with clinical safety, medical monitoring, and clinical research and trial design and conduct. Medical personnel are involved in making medical judgments within the regulatory parameters of the study.

Task 9. Statistical Design and Analysis and Reporting

The CO assets this task is predominately R&D or in support of R&D. This task requires expertise in biostatistics, epidemiology, clinical research and study design. The biostatistical contract staff is integrated into the design and development of clinical trials from the beginning. and often co-publishes with the investigators.

The remaining tasks call for information technology or general administrative work.

The CO asserts that he determined the great majority of the full time equivalents and the direct labor costs in year 1 of the contract are allocatable to R&D work. The CO asserts that a NAICS code for consulting services in inappropriate here, and consultants study a problem, propose a solution and leave, but are not involved in the implementation of the substantive work. Here, this contract calls for the contractor personnel to be actively involved in NIDCR's work.

IV. Discussion

A. Timeliness

Appellant filed the instant appeal within 10 days after NHLB issued the solicitation. Thus, the appeal is timely. 13 C.F.R. §§ 121.1103(b)(1); 134.304(a)(3).

B. Standard of Review

Appellant has the burden of proving, by a preponderance of the evidence, all elements of its appeal. Specifically, it must prove the CO's NAICS code designation is based on a clear error of fact or law. *NAICS Appeal of Durodyne, Inc.*, SBA No. NAICS-4536, at 4 (2003); 13 C.F.R. § 134.314. The correct NAICS code is that which best describes the principal purpose of the services being procured, in light of the industry description in the *NAICS Manual*,[1] the description in the solicitation, and the relative weight of each element in the solicitation. *Durodyne*, SBA No. NAICS-4536, at 4; 13 C.F.R. § 121.402(b).

C. The Merits

The NAICS code designated by the CO, 541712, Research and Development in the Physical, Engineering, and Life Sciences (except Biotechnology), covers:

> [E]stablishments primarily engaged in conducting research and experimental development (except biotechnology research and experimental development) in the physical, engineering, and life sciences, such as agriculture, electronics, environmental, biology, botany, computers, chemistry, food, fisheries, forests, geology, health, mathematics, medicine, oceanography, pharmacy, physics, veterinary and other allied subjects.

2007 NAICS Definitions, at www.census.gov/naics/2007/def/ND541712.HTM. The SBA regulations governing size standards include the following footnote for NAICS code 541712:

> "Research and Development" means laboratory or other physical research and development. It does not include economic, educational, engineering, operations,

[1] Executive Office of the President, Office of Management and Budget, *North American Industry Classification System Manual* (2007).

> systems, or other nonphysical research; or computer programming, data processing, commercial and/or medical laboratory testing.

13 C.F.R. § 121.201, fn. 11(a).

Appellant's requested NAICS code, 541690, Other Scientific and Technical Consulting Services, covers:

> [E]stablishments primarily engaged in providing advice and assistance to businesses and other organizations on scientific and technical issues (except environmental).

2007 NAICS Definitions, at www.census.gov/naics/2007/def/ND541690.HTM.

A review of the tasks in the SOW leads to the conclusion that the work to be performed here is all an integral part of the R&D studies that NIDCR will conduct. The contractor's staff will be part of the work to undertake the studies from the very beginning, taking part in the conception and design of the studies, and making the feasibility assessments. The contractor will make the site assessments that are critical to the success of the clinical trials. The contractor will train the staff that will conduct the studies. The contractor will also provide specimen storage, preclinical product testing, and QA monitoring support. The contractor will also provide the safety monitoring during the trials, assist in preparing reports for the FDA, and assist in the preparation of the final analyses of the studies.

It is thus clear that this SOW does in fact call for research work. The tasks the contractor will perform are all vital parts of the conduct of NIDCR's research. The planning, training, storage of specimens, safety monitoring and assessments are all part of the clinical trials themselves. They are not the functions of a consultant, simply providing advice and assistance to the government. The tasks required are very much a part of the trials themselves, and are thus properly categorized as research.

The thrust of Appellant main argument is that the characterization of the work in this SOW as research is not correct, rather, this procurement is in support of research. Appellant argues that this procurement is not about the conduct of research or experimental development in sciences to produce a product or service. Therefore, it is more properly treated as consulting services. However, I must conclude after reviewing the RFP that research is precisely what this procurement seeks. The procurement seeks a contractor to perform some of the tasks integral to and essential for the conduct of research and clinical trials.

Appellant's cited SIC appeal decisions are likewise unavailing.[2] The procurement in *SIC Appeal of Information Ventures, Inc.,* SBA No. SIC-4259 (1997) was to establish a center for the assessment of health risks, and the SOW there required the contractor to identify and select experts; collect, analyze, and summarize scientific literature for the center staff; maintain

[2] Where appropriate, OHA's case precedent, decided under the prior SIC system, will apply to NAICS code appeals. *NAICS Appeal of Phoenix Scientific Corporation,* SBA No. NAICS-4416, at 8 (2000).

databases, produce a website, organize meetings, handle the accounting, and do various other tasks. In ruling that the predecessor of NAICS code 541712 was not appropriate for that work, the Administrative Judge noted, "the procurement does not contemplate that the successful contractor will engage in *any* commercial physical or biological research." *Information Ventures*, SBA No. SIC-4259, at 4 (emphasis added). Because the application of *Information Ventures* here is premised on a finding that the instant procurement calls for *no research work at all*, a finding which, for the reasons given above I decline to make, I must conclude that decision is inapplicable to the instant procurement.

In *SIC Appeal of The Cadmus Group, Inc.*, SBA No. SIC-3315, at 9 (1990), the SOW contained repeated use of the words "research" and "development" that, on analysis of the actual tasks required of the contractor (as opposed to the agency), the Administrative Judge determined was "misleading." The SOW in the instant procurement, however, cannot be so characterized. Further, the SOW in *Cadmus*, while not totally devoid of true research and development tasks, contained many administrative tasks and many tasks that were "the evaluation of research strategies and activities" which, the Administrative Judge concluded, "must be distinguished from the actual conduct of the research itself." *Cadmus*, SBA No. SIC-3315. at 9-10. That is not the case with the SOW in the instant procurement. Accordingly, because of these factual differences, I find *Cadmus* inapplicable to the instant procurement.

Therefore, the research and development NAICS code, 541712, is the most appropriate code.

Accordingly, I conclude that Appellant has failed to demonstrate clear error on the part of the CO's NAICS code designation, and that the appropriate NAICS code for this procurement is 541712, with a corresponding 500 employee size standard.

V. Conclusion

For the above reasons, the Contracting Officer's NAICS code designation is AFFIRMED. The instant appeal is DENIED.

This is the final decision of the Small Business Administration. *See* 13 C.F.R. § 134.316(b).

CHRISTOPHER HOLLEMAN
Administrative Judge