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Matthew Portnoy, Ph.D.
SBIR/STTR Program Coordinator
National Institutes of Health
U.S. Department of Health and Human Services
6705 Rockledge Drive, Suite 350
Bethesda, MD 20892
mportnoy@mail.nih.gov

Subject: NIH Indirect Cost Rate Rulemaking and Training

Dear Mr. Portnoy:

As the Executive Director of the Small Business Technology Council (SBTC), I've recently learned of issues with indirect cost rates for SBIR companies funded by the National Institutes of Health (NIH). It appears NIH has significantly changed its financial review criteria for indirect cost rates. This lowers payments on NIH grants, putting SBIR companies in financial jeopardy for existing grants, as well as adversely impacting future grants. It appears these criteria are not consistent with the Federal Acquisition Regulations (FAR) and may not have followed proper Rulemaking Processes, as required by the Administrative Procedures Act. I am looking for some guidance from you as to what to tell these companies. What can be done to make sure rate review determinations are done on a consistent and proper basis in compliance with the FAR? And to reduce confusion, training may be necessary to ensure the FAR is followed. This will add to the efficiency of the entire process for all parties.

SBTC encountered similar issues with the Department of Defense. We worked with the Defense Contract Audit Agency (DCAA) to resolve these issues through correspondence and periodic meetings with their management. I would like to pursue a similar process with NIH to ensure your needs are met and SBTC companies are fairly and efficiently compensated for their NIH programs.

BACKGROUND

The NIH is a major player in the Small Business Innovation Research (SBIR) program and is second only to the Department of Defense in the number of awards to small businesses. Consequently, NIH is an extremely important player in generating new jobs for the economy by helping small businesses become established and grow. As the driving force in biomedical research and the American biomedical industry, it is important that NIH policies and procedures, and particularly those that set indirect cost rates, support small business research and financial stability.

The SBTC understands the impact of Congressional funding reductions on NIH's ability to sustain funding to small businesses, both in the number of awards and in the total expenditure. We are also aware of criticism concerning the number of SBIR awards. It is our position that the reduced funding was offset by the caps on grant award size set by the SBIR Reauthorization to allow an equivalent number of awards. We're concerned that costs incurred by NIH's exemption allowing Mega Awards (those Phase II programs over $2,250,000) are impacting reimbursement of indirect costs allowed by the FAR.

We are also concerned that the NIH's rate reviews of indirect costs are not recognizing some costs allowed by the FAR. We understand the SBIR Phase I and II programs are not intended to cover commercialization costs; however, we believe that the FAR requires recovery of allowable, allocable indirect costs. This is particularly important for small business with limited financial resources.

Providing legally allowed indirect cost reimbursement for SBIR companies is imperative now given a number of economic factors that SBIR companies are forced to contend with. These economic factors include:

1. Severe reduction in bank lending to small business. Since 2008 lending to small business has declined by $126 Billion per year.[i] Many extremely large banks receiving TARP funding have stopped lending to small businesses, and many small business credit lines were terminated by their bank.

2. Few venture capital investments in seed and start up enterprises. The majority of these investments have been in software and information technology (IT) industries with the vast majority (74% of the dollars) of these seed and start up deals being made in in just two metropolitan areas (New York City and Silicon Valley). In the third quarter of 2014 there were only 48 VC startup/seed investments, totaling $196.8 million.[ii] Thus, it is almost impossible for companies outside of NY and CA to get seed/startup funding from VCs. Furthermore it is also extremely difficult for companies in most of the US to get growth capital from VCs, as 75% of the VC investment is made in just four states. Thus, for companies in the other 46 states, VC funding is either very difficult to obtain, or not available at all. The medical device industry has been particularly hard hit where the total VC investment in the medical device industry fell from $692.5M in Q2 to $585.6M in Q3, more than a 15% drop in just one quarter. Even worse, VC investment in the biotechnology industry fell from $1,903.7M in Q2 to $1,054.2M in Q3, about a 45% drop; while the number of deals fell from 122 to 110.

3. Both banks and VCs have historically made it particularly difficult for women and minority owned businesses to obtain funding. The SBIR program is exemplary in providing funding for women/minority owned firms, and the NIH is commended for

funding this subgroup of SBIR companies. FAR allowed reimbursement of indirect costs is especially critical for these women/minority owned firms.

We believe that it is in both the NIH's and the SBIR companies' best interest to follow the FAR indirect cost rules to (1) continue to provide a stream of new products and services being commercialized by SBIR companies that will improve the nation's health and Americans' longevity; (2) improve the economy by continuing to create new startups and jobs in companies that utilize the NIH SBIR program; and (3) continue Congressional support for the NIH and its programs through successful development of new devices and drugs being created as the result of the SBIR program.

SPECIFIC POLICY CHANGES IN QUESTION

After receiving a number of concerns from various companies working with different institutes, it appears that either:

1. Rules or guidelines are being promulgated within the NIH/Financial Services Department that have not been reviewed and promulgated according to the Administrative Procedures Act; or

2. Individual Reviewers are working outside of the scope of standard rules and guidelines either due to lack of training or they have chosen to go beyond their purview. Evidence is provided by the following observations. We look to the NIH to be able to clarify if these are either sanctioned decisions, or additional training is required for Auditors/Reviewers.

SBTC's initial concerns are first summarized, and more detail is given below.

1. It appears that indirect rates are being capped at approximately 60-80% for Overhead (OH), 30-40% for General and Administrative (G&A) costs, and approximately 35% for Fringe Benefits, regardless of costs incurred.
2. Costs were deemed as unallowable, beyond those indicated in the FAR.
3. An arbitrary limitation of 15%-25% of "scientific personnel" time was set as the cap for indirect charges.
4. GMP, ISO, and other Quality Assurance and Regulatory costs were disallowed as indirect costs.
5. Indirect labor costs were reallocated to the direct labor pool.
6. Export sales public relations, trade show, and advertising costs were disallowed.
7. Legal Costs and professional fee allocations were disallowed as indirect costs.
8. Invention Disclosure costs were disallowed as indirect costs.
9. Legitimate travel costs are being disallowed.
10. Annual year-end bonuses are being disapproved.

There has been little justification provided for these decisions, other than "Reasonableness" (FAR 31.201-3 Determining reasonableness). The FAR requires a determination of reasonableness based on the following:

["(b) What is reasonable depends upon a variety of considerations and circumstances, including— (1) Whether it is the type of cost generally recognized as ordinary and necessary for the conduct of the contractor's business or the contract performance; (2) Generally accepted sound business practices, arm's-length bargaining, and Federal and State laws and regulations; (3) The contractor's responsibilities to the Government, other customers, the owners of the business, employees, and the public at large; and (4) Any significant deviations from the contractor's established practices.] It does not appear that challenging costs on the basis of "Reasonableness" is consistently applied across NIH Auditors/Reviewers or according to specified guidelines. We are unaware of general rules being promulgated. The NIH Reviewer simply states his opinion that the costs are unreasonable, or at best provides a short discussion of the costs and then determines that in his/her opinion that they are unreasonable. This leaves the companies are left to dispute this conclusion without any facts that determine the basis of the decision.
These will be discussed in greater detail below.

DETAILS OF DECISIONS IN QUESTION

1. Reviewers appear to be capping rates at about 60-80% for OH, 30-40% for G&A, and about 35% for Fringe Benefits. There has been little justification provided, other than one of "Reasonableness." Based on discussions with many company executives with non-SBIR experience, these rates are not sufficient for sustainable operation and do not reflect variances in business models and overhead structures. SBTC believes that artificial caps may doom some innovative companies to failure, leading to pre-selection screening of SBIR firms based on financial resources rather than innovation. Artificial caps on indirect cost rates that are not based on actual cost incurred are especially inappropriate for small businesses in pre-product development, where processes and overhead structures are fundamentally different from those of large, product-rich companies. This is the nature of innovation-based organizations. Rather than imposing rate caps, reviews should identify FAR-allowable indirect costs and allow individual companies to optimize their business model and structure.

   The SBTC would like to discuss the caps issue with NIH and find a solution that is consistent with the FAR and does not adversely impact small businesses.

2. SBTC is particularly concerned about various costs being considered Unallowable, much beyond the costs listed in http://oamp.od.nih.gov/dfas/indirect-cost-branch/indirect-cost-submission/unallowableunallocable-costs. We would like to understand what other rules or guidelines have been promulgated that go beyond the FAR and the above website in determining Unallowable costs.

3. Reviewers have placed a cap on the amount of time that "Scientific" or "Direct" personnel may charge to OH and G&A costs. In a small business, personnel must perform many tasks, including administration, human resources management, information technology, regulatory

compliance, Quality Assurance, Bid & Proposal, training, inventory handling and control, etc. Performance of these functions varies from company to company, and depends on the skills of the "Scientific Personnel" and the needs of the company. SBTC would like to understand the motivation for the 15%-25% cap on OH and G&A tasks and the process for imposing this on company personnel.

4. It appears that various Quality Assurance costs (GMPs, GCP, GLP, and particularly ISO system costs) are sometimes deemed Unallowable as "commercialization" costs. NIH explicitly requires that scientific work be compliant with QA procedures. We do not understand how costs associated with compliance to a program requirement could be deemed unallowable. This appears to be a relatively new phenomenon as a number of these companies have been reviewed for years and this has never been an issue before. These QA systems are required, for example, to perform human trials. SBTC is requesting information on the guidelines used to determine allowability of these costs.

5. NIH is requiring some indirect labor be moved to direct labor pools. This appears be a direct violation of FAR 31.203 -- Indirect Costs ["An indirect cost is any cost not directly identified with a single, final cost objective, but identified with two or more final cost objectives or an intermediate cost objective. It is not subject to treatment as a direct cost."]. There are examples where NIH personnel directed reallocation of up to 75% of the proposed indirect labor dollars to the direct cost base. Is there a new NIH rule that is not part of the FAR, or is this a matter of training of the reviewers?

6. It appears NIH is disallowing all costs associated with commercial sales, including those associated with international sales. FAR 31.205-1 (d) (2), clearly states "Costs of activities to promote sales of products normally sold to the U.S. Government, including trade shows, which contain a significant effort to promote exports from the United States" are allowable. This is particularly important for newly developed SBIR products "sold to the US Government," which are frequently sold in Europe prior to being sold to non-Government entities in the US. It is US Government policy to promote the sale of American made products overseas. NIH policies appear to be inconsistent with government policy, as well as the FAR. Considering requirements for commercialization of SBIR products and services, compliance with the FAR for export sales is critical for SBIR success.

7. NIH is disallowing legal and other services cost. Quality Assurance consultant costs were disallowed as being 'Phase III' activities. SBTC would like information on the guidelines used to disallow various consulting costs.

8. Even though required by the grant, Invention Disclosure costs were disallowed as indirect costs. The SBTC companies are at a loss as to what they should do?

9. Travel costs are constantly challenged, even when the costs are consistent with the FAR. SBTC would like clarification on how travel costs are evaluated by NIH personnel.

10. NIH is now challenging bonus payments, even though they were previously allowed, some for many years or over a decade. Incentive and traditional year-end bonus payments are a critical element of employee motivation and compensation. These are clearly expenses related to employment and a company's ability to attract and retain critical personnel. Also perplexing are situations where the owner takes a very low salary to keep the company solvent, and he/she cannot take a small year-end bonus when reasonable for the services rendered and not a distribution of profits (FAR 31.205-6(a)(6)(A)).

Some of these issues may be the result of new policies put in place by the NIH. Others may relate to individual variations among Auditors/Reviewers. SBTC believes it would be helpful to discuss the implementation of these new rules/policies, and the actual impact of the practices on small businesses. We would like to ensure that small business innovators are able to meet NIH and SBIR objectives. We would also like to assist SBIR companies and the NIH to most efficiently foster innovation and enhance America's health care system

I thank you for taking the time to consider these issues. We would be happy to discuss these and other items with the appropriate people at the NIH. We would like to resolve these issues quickly and efficiently. I look forward to talking with you soon.

Jere W. Glover
Executive Director
Small Business Technology Council.

[i] http://condor.depaul.edu/rcole/pdfs/BankSmallBizLoans2013Q2.pdf
[ii] https://www.pwcmoneytree.com/CurrentQuarter/BySoD