

ORIGINAL ARTICLE

INCREASING RESEARCH CAPACITY AT THE NEW ENGLAND SCHOOL OF ACUPUNCTURE: BUILDING GRANTS MANAGEMENT INFRASTRUCTURE

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A significant practical, yet perhaps under-appreciated, barrier to a more active role of complementary and alternative medicine (CAM) institutions in research is the organizational infrastructure required for submitting and managing research grants.

In this article, we discuss how the New England School of Acupuncture, in collaboration with the Harvard Medical School Osher Institute and with the support of a Developmental Center for Research on Complementary and Alternative Medicine grant

awarded by the National Center for Complementary and Alternative Medicine of the National Institutes of Health, developed its grants management infrastructure and increased its research capacity. We highlight initiatives that have been successful, challenges we have encountered, and lessons we learned that may be relevant to other CAM institutions that may wish to develop a research program. (*Altern Ther Health Med*. 2008;14(1):56-64.)

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Despite increased investment and growth in research evaluating complementary and alternative medicine (CAM), only a small proportion of this research has been conducted by CAM institutions within a collaborative framework that integrates the expertise and clinical experience of CAM professionals in all phases of the research process—from study conception and identification of specific hypotheses to developing treatment interventions, choosing outcomes measures, and interpreting results. An even smaller proportion of this research has been independently initiated by CAM institutions. A significant practical, yet perhaps under-appreciated, barrier to a more active role

of CAM institutions in research is the organizational infrastructure required for submitting and managing research grants.

In 2003, the National Center for Complementary and Alternative Medicine (NCCAM) of the National Institutes of Health (NIH) launched a new program—Developmental Centers for Research on Complementary and Alternative Medicine (DCRC)—that was specifically aimed at increasing research capacity and activity at CAM institutions. The DCRC program is structured around partnerships between CAM and conventional medical research institutions. In this collaboration, CAM partners provide the modality expertise, clinical experience, and cultural perspective needed to implement research studies that accurately reflect traditional practices and values. Conventional partners provide expertise in the conduct of scientifically sound research and institutional-level research management. The broad goals of the DCRC program are to (1) increase CAM research activity at CAM institutions, (2) promote research expertise and develop research infrastructure within the CAM community, and (3) support enhanced communication and partnership between CAM and conventional medical research institutions so that established conventional researchers will gain the clinical and cultural perspective needed to undertake CAM research.

The New England School of Acupuncture (NESA)—in partnership with the Harvard Medical School (HMS) Osher Institute and 2 other HMS-affiliated institutions, Dana Farber Cancer Institute and Children's Hospital Boston—was awarded a DCRC grant in the first year of the program. In this article, we share our experiences during the first 3 years of our DCRC program

building a sustainable, collaborative CAM research program, centered around Oriental medicine (OM) and based at NESAs. We begin by first describing NESAs, the reasons it chose to develop a research program, and the history of collaboration between NESAs and the HMS Osher Institute that laid the foundation for this DCRC and shaped its specific aims. We then focus the majority of this article on describing our progress to date with a number of DCRC-supported initiatives directed at developing research management infrastructure at NESAs. We highlight initiatives that have been successful, challenges we have encountered, and lessons we learned that may be relevant to other CAM institutions that may wish to develop a research program. In a follow-up to this article (which will appear in the Mar/Apr 2008 issue of *Alternative Therapies in Health and Medicine*), we will discuss a parallel series of initiatives centered around research education/training for NESAs faculty and students that were also designed to increase the long-term research capacity at NESAs.

THE NEW ENGLAND SCHOOL OF ACUPUNCTURE AND PRIOR COLLABORATIONS WITH THE HARVARD MEDICAL SCHOOL OSHER INSTITUTE

NESA is one of the oldest colleges of OM in the United States. Founded in 1975, its early mission emphasized OM education and clinical service. NESAs master's-level degree programs center on Chinese- and Japanese-style acupuncture and Chinese herbal medicine. The more than 50 faculty members at NESAs collectively embody a wealth of clinical and teaching experience based on training in Asia as well as the West; many are nationally and internationally recognized leaders in their field. NESAs current student body totals 170; most begin the OM training program with professional experience in other careers. To date, NESAs has graduated more than 1000 practitioners, many of whom have made significant contributions to the field, including founding other OM colleges, establishing acupuncture clinics within conventional medical settings, developing drug detoxification programs, and taking senior roles in state and national OM professional organizations.

Recognizing the importance of research in shaping the future of OM, the valuable clinical and theoretical insight NESAs faculty members and students could provide to inform this research, and a growing interest among NESAs faculty members in participating in research, NESAs president and board of directors established a research program in March of 2000. Key goals of the program were to (1) establish NESAs as a significant contributor to the field of OM research, actively engaging its faculty members in the scientific evaluation of all branches of OM, including acupuncture, Chinese herbal medicine, manual therapies, and meditative exercise; (2) provide faculty and staff members opportunities for advanced training/study through collaborative research and scholarly exchange with leaders in the fields of both conventional and complementary medicine; and (3) provide opportunities for research for students in both the current master's-level programs and an eventual doctoral program. In 2002, when the DCRC program was announced, NESAs research program was still in its early stages of development.

The decision to establish a formal developmental center with NESAs as the CAM institution and the HMS Osher Institute as the more experienced research partner was based on shared institutional goals and values and a history of prior successful collaboration in CAM research and CAM education. The mission of the HMS Osher Institute, also known as the Division for Research and Education in Complementary and Integrative Medical Therapies, includes CAM research, CAM education, and CAM/integrative clinical care. Within the scope of the Osher Institute's commitment to CAM, OM is a particular strength, with an active research portfolio in Asian medicine and healing. NESAs and the Osher Institute's shared goals, a mutual appreciation for the potential synergy resulting from collaboration, and the geographical proximity within the greater Boston area led to a number of collaborations in the years that preceded the DCRC. With respect to acupuncture research, NESAs faculty members served as research or clinical collaborators on a number of NIH-funded grants awarded to the Osher Institute and its predecessor, the Center for Complementary and Alternative Medicine Research and Education (CAMRE, which was originally based at Beth Israel Deaconess Medical Center). These studies addressed a broad range of clinical conditions, including acute low back pain, chronic low back pain, repetitive stress disorder, and irritable bowel syndrome, as well as methodologic studies to explore the nature and effect of acupuncture placebo. Additional NIH and private grants supported collaborations between NESAs and other HMS-affiliated institutions, including the Dana-Farber Cancer Institute and Massachusetts General Hospital; these studies evaluated other OM modalities such as tai chi and Chinese herbal medicine. Finally, faculty at both the Osher Institute and NESAs have participated in CAM research training and educational initiatives at each other's institutions. NESAs faculty members have lectured regularly in HMS's Fellowship Training Program in CAM, in continuing medical education conferences, and in medical student courses. Reciprocally, 2 Osher faculty members have held joint appointments at NESAs and have taught the Foundations of Research course required for all acupuncture students.

Despite NESAs growing commitment to research and its active participation in a number of collaborative research studies, prior to the DCRC program, NESAs had yet to submit an NIH grant in which one of its faculty members served as principal investigator and its administrative and financial staff members managed the award. One key barrier that significantly limited NESAs ability to establish a more autonomous program capable of initiating and managing government-funded research studies was its lack of staffing for and experience with overseeing administrative and financial matters related to research grants. Prior to the DCRC program, NESAs research staff was limited to a part-time director, a part-time research assistant, and a part-time controller who, in addition to managing the administration of research projects, administered all of NESAs finances as well as human resource matters. After describing the overarching goals and partnerships for our DCRC program, we focus the core of

this article on specific DCRC-supported initiatives that were developed and implemented in order to build an independent grants management program at NESAs.

OVERARCHING AIMS, GOALS, AND STRUCTURE OF THE "NESAs ACUPUNCTURE RESEARCH COLLABORATIVE"

With an understanding of NESAs strengths and weaknesses and an awareness of the resources afforded through collaborations with HMS-affiliated institutions, we defined 3 overarching aims/goals to guide and structure our developmental center:

1. *Develop NESAs clinical research infrastructure and its capacity to sustain a creative and productive clinical research program that critically evaluates the diversity of OM practices, initially emphasizing Japanese- and Chinese-style acupuncture.* Specific aims/goals discussed in more detail below include (a) developing pre- and post-award grants management infrastructure with mentoring from HMS and Harvard University (HU); (b) continuing to develop NESAs faculty and student research knowledge and skills through collaboratively developed formal training/education courses, seminar series, and a variety of mentored pilot study programs; and (c) developing human subjects compliance capacity with mentoring from HMS.
2. *Conduct 3 collaborative pilot studies (2 clinical trials and 1 methodological study) that synergistically evaluate acupuncture as an adjunct therapy for adolescent and adult women's health conditions.* One study evaluates whether Chinese-style acupuncture is effective in treating chemotherapy-induced neutropenia in women with gynecological cancer. A second study evaluates whether Japanese-style acupuncture is effective for chronic pelvic pain associated with endometriosis in young women. A third methodological study develops and evaluates the validity and reliability of an OM-structured interview instrument, a tool central to determining OM diagnoses in the context of clinical trials. The rationale, design, and preliminary results of these pilot studies are not reviewed in this article but are discussed elsewhere.¹⁴
3. *Strengthen already ongoing collaborations between NESAs, HMS (namely through the Osher Institute), and HMS-affiliated institutions (Dana Farber Cancer Institute and Children's Hospital) as a commitment to a long-term collaborative research program that employs the highest research standards to evaluate traditional OM interventions and contributes to the development of sound methodologies and instruments to facilitate OM research.* This collaboration includes (a) joint participation in 3 developmental studies (see 2, above), as well as future projects based on preliminary findings; (b) joint participation in inter-institutional seminars, training, and education programs; and (c) communication between research administration personnel at NESAs and HMS resulting in the development of research administration infrastructure and procedures.

Structure of the NESAs Acupuncture Research Collaborative

To accomplish our center's aims, the DCRC is structured around 2 central cores: an Administrative Core and a Clinical Trials Core, each composed of key administrative and academic personnel representing both NESAs and the HMS Osher Institute. Both cores were created in compliance with the NIH Program Announcement and serve as advisory teams to monitor and assist with administrative and clinical trial issues while establishing the infrastructure required to guide the proposed projects at the CAM institution. The Administrative Core, in addition to overseeing essential administration and coordination for the 3 developmental studies, has primary oversight over all activities related to NESAs research-related educational/training initiatives and development of research management infrastructure. The Clinical Trials Core provides essential biostatistical, data management, and trial methodology support for the developmental studies and, through regular meetings with teams representing each study, serves as another vehicle for training NESAs personnel in all aspects of clinical research. Additional guidance and oversight for our center is provided by (1) an external advisory committee composed of 4 nationally recognized senior researchers, including our appointed NIH program officer; (2) an internal steering committee composed of co-leaders of all developmental studies and cores; and (3) representatives of the Office of Clinical Research Affairs at NIH (because the DCRC program is funded through a U-19 cooperative agreement program). Finally, formal arrangements were established that allowed NESAs administrative staff members to consult with administrative staff members at HUs Office of Sponsored Research (OSR) and Harvard Medical School's Sponsored Programs Administration (SPA) and Financial Operations Administration (FOA) offices on an as-needed basis. The Figure outlines the relationship between the cores, the developmental projects, and the other advising entities.

The development of a sustainable, independent research program at a CAM institution such as NESAs that has limited research experience and minimal research infrastructure requires significant knowledge transfer and mentorship in a variety of interdependent areas. Embedded within the collaborative model illustrated in the Figure was a carefully designed mentoring scheme to facilitate knowledge transfer from Harvard to NESAs personnel in all aspects of research. The following relationships are 4 specific examples of this mentoring system: (1) NESAs research director, also the DCRC's overall principal investigator, was paired with the Osher Institute's director of research and mentored in all aspects of research methodology, program management, and leadership skills; (2) NESAs chief financial officer was paired with the Osher Institute's executive director and mentored in the development of a research financial accounting system and all aspects of NIH pre- and post-award management and reporting; (3) NESAs research manager was paired with the Osher Institute's research manager and mentored in all aspects of project coordination and management; and (4) NESAs faculty involved in faculty and student research training were paired with the Osher Institute's associate

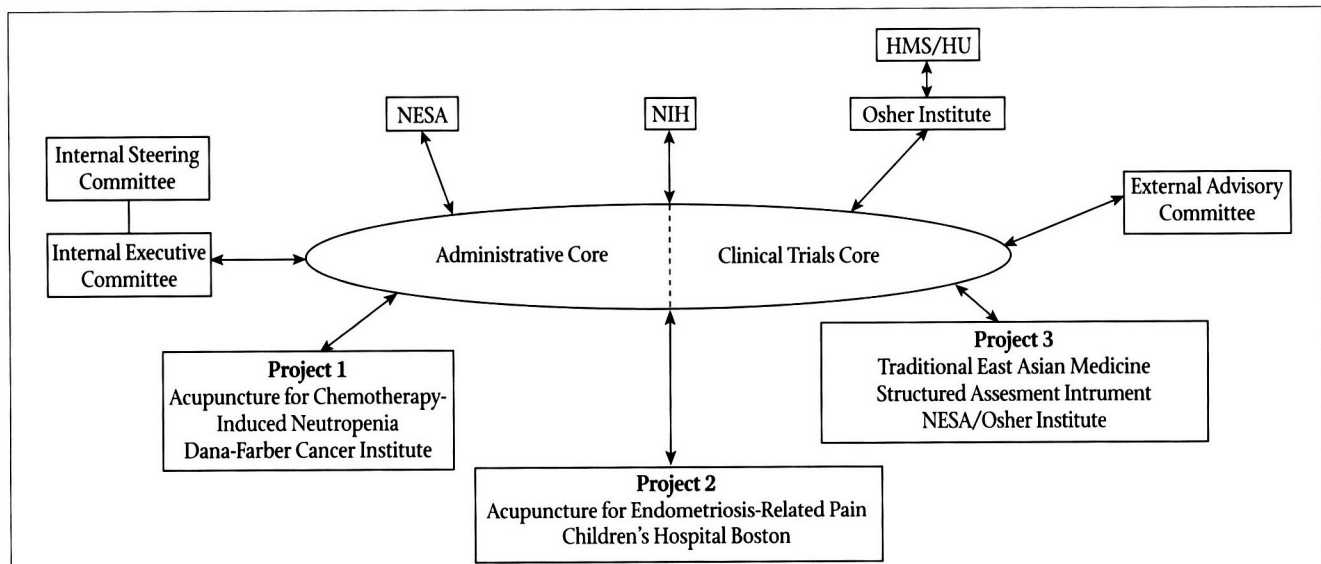


FIGURE Relationship of Administrative and Clinical Trials Core for the DCRC*

*DCRC indicates Developmental Centers for Research on Complementary and Alternative Medicine; HMS/HU, Harvard Medical School/Harvard University; NESAs, New England School of Acupuncture; NIH, National Institutes of Health.

director of clinical research and mentored in course content and curriculum development. Furthermore, as required by the DCRC guidelines, each of the 3 developmental studies was co-led by 1 NESAs and 1 Harvard faculty member, which allowed for practical on-the-job mentoring. This training was further facilitated by regular meetings with the Clinical Trials Core, which provided guidance for each of the studies. Finally, additional mentoring and support was afforded through access to formal training programs made available to NESAs personnel by HU/HMS and through input from NCCAM/NIH advisors and from members of our External Advisory Committee.

In summary, the accomplishment of the goals of our DCRC required an extensive team of collaborators and a carefully designed mentoring system. Below we illustrate the application and results of this collaboration with respect to the development of research management infrastructure at NESAs.

BUILDING GRANTS MANAGEMENT INFRASTRUCTURE

Prior to our DCRC program, NESAs had virtually no experience in grants administration and a very limited grants management staff. Because NESAs's financial and human resource technology requirements were very simple, its accounting systems were based on software and systems typically used for small businesses. These systems were not designed to manage and account for multiple, multi-year grant budgets, each with numerous consortium agreements. Furthermore, NESAs had no experience developing consortium agreements with collaborating institutions, had yet to negotiate a facilities and administration (F&A) cost rate proposal, and had not yet learned how to comply with NIH procedures such as drawing down and transferring awarded funds and completing annual financial status reports. Consequently, a major focus of the DCRC was to establish a for-

mal sponsored programs office at NESAs capable of independently managing NIH awards.

With the Osher Institute serving as liaison, NESAs's first step was to gain access to the expertise of HMS and its parent, HU, to consult on various aspects of grants management. Specifically, NESAs consulted with staff members in the HMS Sponsored Programs Administration office for all pre-award related planning, with HMS Financial Operations Administration for all cash management and fund establishment issues, and with the HU Office of Sponsored Research for all post-award management and reporting issues. NESAs's ability to take advantage of the existing expertise at HU/HMS to assist NESAs in developing its own infrastructure (albeit much smaller) has been priceless.

In addition to helping NESAs develop its research infrastructure, the HMS Osher Institute provides NESAs with advice and guidance in handling the day-to-day responsibilities of managing NIH funds. The DCRC Administrative Core worked closely with the Osher Institute and HMS to develop a checklist for grants administration/management. The purpose of this checklist, based on policies and procedures already established by HU/HMS, is to guide the development of NESAs's grants administration infrastructure and to prioritize associated activities. Items on the checklist include initiatives relevant both to the initial "set-up" stage of our DCRC and to ongoing activities conducted on a weekly, monthly, or annual basis that are necessary in order to manage the program in compliance with NIH guidelines. The checklist also includes action items relevant to the end of an awarded grant period as well as for the submission of new grant applications. This checklist has both guided the development of our grants management program and provided a means to track our progress. The checklist in its entirety, as well as the progress NESAs's DCRC has made to date in addressing these tasks, is summarized in the Table.

TABLE New England School of Acupuncture Grants Management Checklist*

Setup			
Yes	No	In Progress	Item
✓			Develop chart of accounts for grant components (Projects 1-3, Administrative Core, Clinical Trials Core)
✓			Establish, fine-tune, and customize computerized financial management system to allow accurate, detailed, and up-to-the-minute reporting of financial status and staffing distribution for all projects
✓			Review NoGA for awarded funds and revise budgets as necessary
✓			Identify allocation of funds in budget and assign (payroll, etc)
✓		Ongoing	Identify and appropriately report cost sharing
✓			Generate subcontracts
✓			Set up consultant payment system and inform consultants how to bill NESAs
✓		Ongoing	Develop and implement set of institutional policies regarding grant management (eg, budgeting, cost transfers, cost sharing, cash management)
Daily/Weekly			
Yes	No	In Progress	Item
✓			Bill payment with assignment of payments to correct accounts
✓			Assign payroll charges when cost incurred
✓			Make sure that all costs are allowable and reasonable
✓		Ongoing	Identify whether subcontractors are billing on a timely basis and follow up as necessary
Monthly			
Yes	No	In Progress	Item
✓		Ongoing	Review charges to accounts and make any journal entries necessary (note: journals need to be made with in 90 days of date of cost incurrence)
✓		Ongoing	Compare budget to actual and identify critical differences; make necessary corrections
✓		Ongoing	Generate reports by account—current period and cumulative actual vs budget
		Ongoing	Produce and verify effort reports; have primary investigator sign off; maintain file for audit purposes
		Ongoing	Assign allocable costs according to policy (allowable and reasonable)
		✓	Prepare reporting package for review by NESAs management and DCRC executive committee
✓			Maintain “other support” data for all faculty and oversee preparation of other support pages for grant applications
✓		Ongoing	Make recommendations for cost saving and rebudgeting
Annually			
Yes	No	In Progress	Item
✓			For annual progress report, estimate level of carry forward and provide explanations as required
✓			Prepare and file annual FSR as/if required by NIH
✓			Make necessary requests for carry forward
✓		Ongoing	Prepare for A133 audit
✓			Recast F&A cost estimate
✓		Ongoing	Recast budget for upcoming year taking carry forward into consideration
✓		Ongoing	Assess and improve the efficiency of systems, platforms, and processes
End of Grant			
Yes	No	In Progress	Item
✓			Prepare final FSR and send electronically to NIH within deadline
Ad Hoc			
Yes	No	In Progress	Item
✓		Ongoing	Act as liaison with sponsoring agencies with regard to fiscal issues
✓		✓	Maintain ongoing contact with primary investigator and project leaders to identify intellectual property issues; policies for management of intellectual property should be established

TABLE New England School of Acupuncture Grants Management Checklist* (continued)

Grant Development

Yes	No	In Progress	Item
✓		✓	Identify funding opportunities
✓			Develop familiarity with NIH resources, including websites
✓			Reading and understanding an NIH RFA/RFP/program announcement
✓		✓	Understanding requirements of PHS 398 application forms and appropriate progress report forms, training current and future investigators
✓			Understanding modular vs non-modular budgeting systems
		✓	Understanding SNAP, the different types of federal grants, and other processes and procedures for the management of grants
✓			Preparing grant applications independently
✓		Ongoing	Negotiating, setting up, and managing subcontracts
✓		Ongoing	Review documents for completeness, formatting, accuracy, and compliance
✓		✓	Understanding and supporting the IRB process, IND issues, FDA approvals, etc
✓		✓	Develop policies and procedures for institutional review and sign off on an application and progress report
✓		Ongoing	Develop relationships with appropriate program and financial officers at NIH

Compliance

Yes	No	In Progress	Item
		✓	Develop policies and procedures for institutional compliance in accordance with OMB Circular A-21 (Cost Principles for Educational Institutions)
		✓	Develop policies and procedures for institutional compliance in accordance with DHHS Part 74 (Uniform Administrative Requirements for Awards and Subawards to Institutions of Higher Education)
		✓	Understand A133 audit requirements
		✓	Develop policies and procedures to meet all compliance issues, including lobbying, drug-free workplace, debarment and suspension, integrity in science, conflict of interest, research misconduct, etc
✓		Ongoing	Regularly review NIH/NCCAM policies and procedures for updates

Staff Training

Yes	No	In Progress	Item
✓		✓	Keep list of training in which all staff members participate

*NOGA indicates Notice of Grant Award; NESAs, New England School of Acupuncture; DCRC, Developmental Centers for Research on Complementary and Alternative Medicine; FSR, financial status report; NIH, National Institutes of Health; F&A, Facilities and Administration; RFA/RFP, Request for Application/Request for Proposal; PHS, Public Health Service; SNAP, Streamlined Non-competing Award Process; IRB, Institutional Review Board; IND, Investigational New Drug; FDA, US Food and Drug Administration; OMB, Office of Management and Budget; DHHS, US Department of Health and Human Services; NCCAM, National Center for Complementary and Alternative Medicine.

REPRESENTATIVE GRANTS MANAGEMENT INITIATIVES

To illustrate some of the steps that are involved in developing an NIH-compliant grants management program more fully, we briefly describe below the process of addressing 3 of the items included in our grants management checklist: (1) estimating and negotiating NESAs's facilities and administrative (F&A) cost rate, (2) managing and systematizing the funds "drawdown" process, and (3) reporting annually the grant's financial status with a Financial Status Report (FSR).

Establishing the F&A Cost Rate

Under federal grant guidelines, institutions like NESAs are reimbursed for allowable direct costs associated with their various grants. In addition, the institution is allowed to recoup an amount

to help offset indirect costs that are incurred by the institution as a result of the grant. For example, NESAs might incur general and administrative expenses in the process of administering the grant that are difficult to allocate back to the grant. Similarly, there may be operations and maintenance expenses, library expenses, and academic administrative expenses that should be reimbursed to NESAs but that are difficult to identify specifically. These expenses are collectively known as F&A expenses and are reimbursed to the institution based on a negotiated rate and formula. Although these payments are reimbursements of expenses already incurred by the institution and therefore are not income, they can be a significant resource to the institution.

Because NESAs receives less than \$10 million in direct sponsored research costs, it is eligible to determine its F&A cost rate

using the "simplified method." The process of determining the F&A rate is far from simple, however. Using NESA's audited financial statements as a base, all of NESA's costs are classified, excluded, or otherwise adjusted to determine the federally allowable direct and indirect cost totals. Under the simplified method, total indirect costs are divided by total direct salaries and wages to determine the F&A rate. That rate is then applied to actual salary and fringe benefit costs of a federal grant to calculate the actual dollar amount to be reimbursed under the grant as indirect costs.

Under federal guidelines, all recipients of NIH funds must submit an analysis of their indirect costs to their cognizant agency prior to receiving reimbursement for those costs under the grant. The reimbursement rate determines reimbursements on future grants and may be re-negotiated over several years.

Prior to the DCRC grant, NESA had never established an F&A rate and did not have the knowledge or understanding of the processes required to do so. Immediately following submission of the DCRC proposal, NESA's part-time controller submitted NESA's first indirect cost proposal with mentoring from the HMS Osher Institute and using the basic guidelines from Circular A-21, "Cost Principles for Educational Institutions." The proposal was accepted but was not considered final because NESA was not yet established as a grant recipient. Over the next 2 years, NESA completed 3 additional indirect-cost proposals to support the level of indirect costs expected; the most recent approved proposal is effective until June 2009.

In an effort to develop consistent processes and procedures, NESA has documented the indirect cost proposal process, including supporting annotated spreadsheets. This will ensure that future proposals are prepared in an efficient manner consistent with prior proposals.

Drawdown of Grant Funds

Federal funds cannot be acquired, or drawn down, by grant recipients unless specific procedures are followed with accurate supporting financial records. To comply with these procedures, NESA had to modify both its accounting and payroll software to track the direct costs incurred for each of the specific projects and cores. Once these changes were made, it was relatively straightforward to run project and core direct cost reports for any given time period. F&A costs were then calculated and added to the total direct costs before drawing down funds. The drawdown process is fully automated, with access through the NIH website and subsequent funds transfers done electronically. Because NESA spent the funds before being reimbursed by the NIH, NESA avoided potential problems from earning interest on federal funds; however, NESA established a non-interest-bearing account to receive grant drawdowns and transferred those funds to its operating account only as required for cash flow purposes.

NESA has established written procedures for funds drawdown, including step-by-step instructions for processing the requests on the NIH website. Today, although the drawdowns have become routine and are executed regularly at the end of each month, the accounting process still requires regular and

careful attention to ensure that appropriate documentation for all costs and drawdowns is available for any subsequent federal audit. NESA also has created written procedures for the PSC 272 Report, filed quarterly, which documents the status of each federal grant's cash position.

Financial Status Report

The Financial Status Report (FSR) is another administrative requirement for federal grant recipients. This report is filed annually for some types of grants, including this DCRC grant, and provides a reconciliation between cash received and costs incurred on any grant. As with the F&A cost rate and the drawdown of grant funds, the process of completing an FSR required extensive preparation of accounting reports and reconciliation with the actual grant budget for the year. There were no guidelines or handbooks on completing an FSR, so NESA relied on assistance from the HMS Osher Institute as well as the NIH help desk. The FSR report required development of several specialized spreadsheets, which have been documented and color-coded to facilitate the preparation of future FSRs. NESA's processes and procedures also have been documented.

DISCUSSION

Prior to becoming a DCRC, when NESA first began exploring the possibility of establishing a formal research program, the 2 biggest challenges it anticipated were developing research expertise among its faculty members and identifying interested conventional medicine research collaborators. The importance of developing grants management infrastructure and the potential challenges inherent in that undertaking were not obvious and were hardly considered. With hindsight and experience from the past 3 years of NCCAM support to develop NESA's grants management infrastructure, the NESA research program and administration now realizes the central role that infrastructure plays in a research institution and that our initial view was naïve.

For smaller CAM institutions like NESA that begin the process of building a research program with only limited financial and administrative infrastructure, the process of developing an autonomous, compliant grants management program can be a Herculean task. First, it requires a commitment by the CAM institution to hire and build an administrative staff that is capable of learning and managing an unusually diverse set of responsibilities and willing to do so. For example, at NESA only 2 individuals (the school's chief financial officer and the research manager) oversee functions including drawing down and managing all grant monies, negotiating institutional F&A rates, developing consortium agreements, generating annual FSRs, developing research grant-related policies, and overseeing more general day-to-day financial and administrative tasks. At larger research institutions, this diverse set of tasks is managed by numerous specialists who are often housed in distinct departments or offices, each with their own trained staff.

Second, building a research program at a CAM institution requires an effective partnership with experienced, committed

mentors who will facilitate the transfer of the significant body of knowledge required for successful grants management and compliance. The quantity and complexity of information that is required to manage federal grants can be daunting initially for research-naïve CAM institutions. In the case of the NESAs Acupuncture Research Collaborative, our chief financial officer and research manager were directly mentored by the executive director and research manager, respectively, at the HMS Osher Institute. During the first year of our DCRC, the NESAs staff members and their HMS mentors often met in person more than once per week, with additional contact by phone and e-mail. This mentoring by the HMS Osher Institute staff was supplemented by access to personnel from the HMS Sponsored Programs Administration office, HMS Financial Operations Administration, and HU Office of Sponsored Research and through training programs offered by HU/HMS, the National Council of University Research Administrators, and other research organizations. In many cases, HU/HMS offices generously shared policies or protocols, which NESAs could then modify to make them appropriate for use within NESAs. Without this generous and enthusiastic support from our Harvard mentors and the resulting transfer of knowledge, it is unlikely that NESAs grants management program would have achieved its current level of autonomy and success.

Finally, the development of infrastructure at CAM institutions requires a significant amount of time and financial resources and consequently may require external support such as subsidies or developmental grants. In the case of the NESAs Acupuncture Research Collaborative, the process has taken more than 3 years, and some components of the grants management infrastructure still are not fully in place. The financial support from NCCAMs DCRC program enabled NESAs to begin the process of building the infrastructure and associated staff support. Specifically, NESAs was able to use grant funding to support salaries for NESAs chief financial officer, the HMS Osher Institute's executive director, and other key administrative personnel at a critical time in this process. Without the DCRC grant, which specifically funded infrastructure development, it would have been extremely difficult, if not impossible, to build this program with the limited resources available at NESAs. However, even with access to these funds and NESAs and HMSs commitment to the program, significant time and financial challenges remain with respect to the sustainability of the program.

The experience of the NESAs Acupuncture Research Collaborative suggests that the DCRC program's goals of building and supporting infrastructure at CAM institutions are achievable. With the support and partnerships afforded by the DCRC program, NESAs has dramatically improved its ability to manage and apply for NIH grants independently. During the initial stages of the program, NESAs relied heavily on HMS for regular administrative support and training. In fact, the development of the initial budget proposal for our DCRC and the management of the award during our first year of funding were largely conducted by the HMS Osher Institute's executive director. With 3 years of shadowing, mentoring, and training, NESAs administrative staff

now works autonomously, only occasionally seeking advice. Frequently, when they do solicit advice, NESAs staff members contact NIH support staff members directly rather than relying on their HMS colleagues. NESAs now has well-documented systems and procedures for many grant-related processes, including generating FSRs, drawing down funds, managing subcontracts, and negotiating indirect costs.

One representative test of our grants management skills occurred near the end of the second year of the DCRC, when NESAs submitted its first NIH R21 grant application with its research director as the primary investigator. NESAs grants management staff oversaw all aspects of budget development, consortium agreement negotiation, human subjects research compliance requirements, and application production. NESAs now has the skills and staff to oversee primary responsibility for such activities and even has begun sharing its experience with other CAM institutions.

The development of a research grants management infrastructure summarized here represents only one of many DCRC-funded initiatives at NESAs that are focused on developing a sustainable, independent research program. Other initiatives include a research education/training program for faculty members and students, development of an OM research library, the establishment of an independent institutional review board to oversee the ethical conduct of trials, and the establishment of a resource development program to help find alternative sources of income to supplement federal grant support for research. Although many of these initiatives are still in their early phases, there are a number of indications that they are or will become successful. For example, NESAs library now has one of the most comprehensive collections and electronically available databases of OM literature in the United States. NESAs newly launched resource development program is helping to identify and solicit funds to support ongoing research. Another measure of our success is the number of faculty members, alumni, and students engaged in research projects. Since establishing our DCRC, more than 75 NESAs faculty members and alumni and 15 NESAs students have participated in some aspect of an externally funded research study, and more than 25 peer-reviewed articles have been published or submitted for publication. NESAs research capacity has grown dramatically.

The NESAs Acupuncture Research Collaborative is the first and only DCRC awarded to an OM school. With NIH support, and the continued collaboration with HMS, NESAs has made significant progress in establishing its research program and the administrative infrastructure necessary to support the program. The long-term sustainability of this program is still uncertain, however. As a new research institution with a relatively small operating budget and limited discretionary funds, NESAs research program remains vulnerable to financial shortfalls such as unfunded grant applications, low student enrollment, and unsuccessful development efforts. NESAs experience may prove to be helpful and serve as a model for other CAM institutions interested in developing research programs. Even with the significant commitment of all parties involved in the

NESA Acupuncture Research Collaborative, NESA's future success will ultimately depend on the continued financial and strategic commitment of NESA, the NIH, and NESA's collaborators.

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Editor's note: A follow-up to this article, "Increasing Research Capacity at the New England School of Acupuncture Through Faculty and Student Research Training Initiatives," will appear in the Mar/Apr 2008 issue of Alternative Therapies in Health and Medicine.

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