NCCAM Pre-Application Teleconference to Discuss Three Funding Opportunity Announcements for Research on the Use of Nonpharmacological, Complementary and Integrative Approaches for Pain and Symptom Management in Military Personnel and Veterans

August 6, 2013

NCCAM Funding Opportunity Announcements:

Clinical Trials and Interventional Studies of Nonpharmacological Approaches to Managing Pain and Co-Morbid Conditions in U.S. Military Personnel, Veterans, and their Families (R01), RFA-AT-14-003, grants.nih.gov/grants/guide/rfa-files/RFA-AT-14-003.html

Pilot and Feasibility Studies of Nonpharmacological Approaches to Managing Pain and Co-Morbid Conditions in U.S. Military Personnel, Veterans, and their Families (R34), RFA-AT-14-004, grants.nih.gov/grants/guide/rfa-files/RFA-AT-14-004.html

Health Services and Observational Studies of Nonpharmacological Approaches to Managing Pain and Co-Morbid Conditions in U.S. Military Personnel, Veterans, and their Families (R01), RFA-AT-14-005, grants.nih.gov/grants/guide/rfa-files/RFA-AT-14-005.html

Both the National Center for Complementary and Alternative Medicine (NCCAM) and National Institute on Drug Abuse (NIDA) are participating in all three funding opportunity announcements (FOAs). VA Health Services Research and Development (HSR&D) is participating only in the R01 Health Services/Observational Studies announcement.

Purpose of the Teleconference: On August 6, 2013, NCCAM convened a pre-application teleconference to provide technical assistance to prospective grant applicants. The teleconference provided an overview of the funding opportunity and explained the peer review process. The teleconference also addressed participant questions received via telephone and e-mail.

Application Receipt Date: October 11, 2013

Teleconference Speakers:
Ranjana Banerjea, Ph.D., M.B.A., VA HSR&D, Scientific Program Manager,
Dave Thomas, Ph.D., NIDA, Health Scientist Administrator
Peter Kozel, Ph.D., NCCAM, Scientific Review Officer
Anita Greene, M.A., NCCAM, Outreach Program Manager (Moderator)

Important information provided about these FOAs by NCCAM and specific questions and answers asked during the teleconference appear below.

Important Information About the Program Announcement:

The purpose of the award is to encourage research on nonpharmacological approaches to symptom management for pain and associated problems (e.g., post-traumatic stress disorder (PTSD), traumatic brain injury (TBI), substance use disorder (SUD), depression, anxiety, and sleep disturbances) among U.S. military personnel and veterans.

Background Information:

1. The wars in Iraq and Afghanistan have been the longest sustained U.S. military operations since the Vietnam era, sending more than 2.2 million troops into battle, and resulting in more than 6,600 deaths and 48,000 injuries. While many service members return home relatively unscathed and report rewarding experiences, others return with varied complex health conditions and find that readjusting to life at home, reconnecting with family, finding work, or returning to school is an ongoing struggle. High rates of TBI, PTSD, pain disorders, and other co-morbid physical and psychological conditions have been documented.

2. The Office of the Army Surgeon General's Pain Management Task Force released their Final Report in May 2010, *Providing a Standardized Department of Defense (DoD) and Veterans Health Administration (VHA) Vision and Approach to Pain Management to Optimize the Care for Warriors and their Families*, and have launched a Comprehensive Pain Management Campaign Plan. One of the objectives specified in the final report is to incorporate complementary and integrative therapeutic modalities into patient-centered plans of care. There has been unprecedented interest in these health care settings in the use of complementary approaches to help active duty personnel and veterans.

3. In a separate effort, the Institute of Medicine (IOM) released a Consensus Report, *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research*. The IOM report encourages Federal and state agencies and private organizations to accelerate the collection of data on pain incidence, prevalence, and treatments. The report also notes that, ideally, most patients with severe persistent pain would obtain pain care from an interdisciplinary team using an integrated approach that would target multiple dimensions of the chronic pain experience—including disease management, reduction in pain severity, improved functioning, and emotional well-being and health-related quality of life.

4. Data from the most recent National Health Interview Survey show that many complementary approaches are used for pain and symptom management by the American public. Research has suggested that some approaches hold promise for helping individuals manage chronic pain conditions and for ameliorating symptoms, but additional research is warranted.

5. NCCAM's Strategic Plan published in 2011 prioritizes research on complementary approaches for pain and symptom management.

Goal of the Initiative:

The goal is to encourage data collection and research on nonpharmacological and complementary or integrative approaches for pain and symptom management in military or veteran populations. Research is encouraged on management of pain and symptoms associated with co-morbid physical and mental conditions (e.g., PTSD, TBI, SUD, depression, anxiety, and sleep disturbances).

Administrative Points Regarding the FOAs:

- The research proposed must be focused on nonpharmacological approaches to pain and symptom management in U.S. military personnel, veterans, or their family members.

- Research related to all branches of the military (e.g., Army, Navy, Marines, Air Force, Coast Guard, Army Reserve, National Guard) and veterans is of interest.

- For these FOAs, research related to individuals who are serving or have served in Operation Enduring Freedom (Afghanistan), Operation Iraqi Freedom (Iraq), and Operation New Dawn is of special interest, due to the growing public health need to address issues in returning troops from war operations.

- For purposes of the FOAs, "complementary, nonpharmacological, and integrative approaches" include, but are not limited to, mind and body interventions such as mindfulness or meditation-based stress reduction approaches, yoga, acupuncture, art therapy, and cognitive-behavioral interventions that are designed to improve both pain management and symptoms of other conditions.

- "Complementary, nonpharmacological, and integrative approaches to health care" could also include multidisciplinary models of care such as pain clinics, Department of Veterans Affairs (VA) hospitals, and clinical health systems that include pharmacological, psychological, and complementary treatment modalities to manage pain and reduce prescription drug use or prevent prescription drug abuse.

- To be responsive to these FOAs, applications proposing to test interventions must measure pain outcome or pain management as a primary outcome variable.

Additional Administrative Points:

- The VA is participating in the R01 Health Services FOA only.

- For R01 applications considered for NIH funding, budgets for direct costs may not exceed $500,000 per year or $2.5 million over a 5-year project period.

- R01 applications considered for VA funding may not exceed $350,000 per year or a total cost of $1.1 million over the life of the project.

- The budget should include funds necessary for up to two key personnel to travel to and participate in an in-progress programmatic/science review, lasting not more than two days and including up to two overnight stays, for each year of the project period.

Information About the Use of the NIH R34 Application Mechanism:

- It is used to support preliminary clinical studies that are needed prior to large clinical trials.

- Applications could include the study of potential biological mechanisms of action or biomarkers used in the context of a future efficacy or effectiveness trial.

- Preliminary studies could focus on early stages of intervention development and the development of supportive material and resources.

- Applications may propose aims of assessing the acceptability, feasibility, safety, and tolerability of interventions, and the adherence to interventions. Interventions must have pain outcome/pain management as the primary outcome variable.

- While randomization may be employed as a methodological approach toward addressing the goal of this announcement, randomized clinical trials to test efficacy are not appropriate for this funding opportunity.

- A strong conceptual model/rationale for why the specific intervention proposed is likely to be beneficial for the clinical condition under study must be included.

- The preliminary data must be compelling enough to support the proposed research.

- Applications should include a letter of support and appropriate institutional clearances for research conducted in DoD or VA sites.

- For specific examples of projects appropriate for the use of this NIH R34 mechanism, please refer to the FOA.

Information About the Use of the NIH R01 Clinical/Interventional Research Projects Application Mechanism:

For specific examples of project types for the use of this mechanism, refer to the FOA.

Information About the Use of the NIH R01 Health Services Research and Observational Application Mechanism:

For specific examples of project types for the use of this mechanism, refer to the FOA.

VA-Specific Information

In order to be eligible for VA funding, all VA eligibility criteria must be met by applicants. (Please see www.research.va.gov and the eligibility criteria for VA Research Support in the VHA Handbook 1200.15.)

Research funds will only be awarded if the principal investigator (PI) and any co-principal investigator (co-PI) have employment status and activities that demonstrate a primary professional commitment to VA. The eligibility of each prospective PI (and co-PI) must be established prior to the funding of a research proposal. The PI (and co-PI) must meet additional requirements—see details in the FOA.

Project proposal applications involving research with children must include an approved waiver that must be obtained from the VA Chief Research and Development Officer prior to application submission.

Application Review Information:

Applicants are strongly encouraged to submit a letter of intent to Dr. Kristen Huntley by September 11, 2013. Briefly, the letter of intent should contain a descriptive title of the proposed study, the names, telephone numbers, and institutions of all key personnel, including the PI, members of the collaborative implementation and evaluation teams, and the number and title of the funding opportunity. Submission of the letter of intent is very helpful, as it provides NIH staff invaluable information, which helps us plan and organize review meetings.

NCCAM will create one or more special emphasis panel(s) (SEP[s]) to review applications submitted in response to the three FOAs. The composition of the panel(s) will reflect the nature of the applications received. In your cover letter, please describe the sorts of expertise you, the PI, think are appropriate to review your application. You MAY NOT recommend potential reviewers BY NAME OR INSTITUTION. Per the Federal Advisory Committee Act, NIH review panels must be diverse in terms of geography, race, gender, and other factors. An effort will be made to have reviewers with VA and DoD expertise on the panel. However, only 25 percent of the panel will be made up of Federal employees.

The date and review platform for the review meeting(s) have yet to be determined. The review meeting will be performed through a teleconference, an in-person meeting, using a secure NIH Web site for chat discussion, or some combination of these platforms.

The criteria for these RFAs are the standard criteria for an NIH research grant. The criteria on which reviewers will base scores are: Significance; Investigator(s); Innovation; Approach; and Environment. Under each of these five criteria are a series of sub-criteria, phrased as questions. Most of these sub-criteria are standard for NIH research grants; however, there are some sub-criteria that are unique to these FOAs.

As for any application, we would strongly suggest that you keep all of the review criteria, including the special criteria, in mind and address them as you prepare your application.

For RFA-AT-14-003 and -004, (Clinical Trials and Intervention Studies of Nonpharmacological Approaches to Managing Pain and Co-Morbid Conditions in U.S. Military Personnel, Veterans, and their Families; and Pilot and Feasibility Studies of Nonpharmacological Approaches to Managing Pain and Co-Morbid Conditions in U.S. Military Personnel, Veterans, and their Families), the criteria are as follows:

Under "Significance," the special criteria are: "Does the project address an important problem or critical barrier to progress in pain management in military or veteran populations? Could the intervention be implemented in a real world setting?"

Under "Environment," the special criterion is: "If research is proposed to be conducted in a DoD or VA setting, does the application provide evidence of appropriate institutional clearance and support from the DoD or VA site?"

For RFA-AT-14-005, (Health Services and Observational Studies of Nonpharmacological Approaches to Managing Pain and Co-Morbid Conditions in U.S. Military Personnel, Veterans, and their Families), the criteria are as follows:

Under "Significance," the special criteria are: "Does the project address an important problem or critical barrier to progress in pain management in military or veteran populations? Is the approach studied practical and does it have potential, if successful, for implementation and integration in other real world health care settings (e.g., in terms of cost of training, staff, office space, and patient burden)?

Under "Approach," the special criterion is: "If research with children is proposed at a VA site by VA investigators, does the application include an approved waiver from the VA Chief Research and Development Office?"

Under "Environment," the special criterion is: "If research is proposed to be conducted in a DoD or VA setting, does the application provide evidence of appropriate institutional clearance and support from the DoD or VA site?"

General Grantsmanship Advice:

- Begin working on your application early. While it is possible to prepare an application very quickly, it takes much longer to prepare a competitive application.
- For those who aren't familiar with NIH grant applications: everything counts, from the (big picture) justification for the proposed research strategy to the spelling and grammar in the application.

- Write your application to address the review criteria.

- Remember that the composition of the review panel is a reflection of the science proposed in the applications. Consequently, the panels can have very broad expertise.

- All reviewers will provide scores for all applications they are not in conflict with. This means that your application should be written so that it could be understood by someone who is not an expert in your field(s).

- Organize your application so that it's easy for reviewers to find information. Write your application so that it's easy to read.

- Follow the page limits laid out in the FOA. Do not use the Appendix to circumvent the established page limits.

- Remember that you, as PI, cannot submit applications directly to NIH; applications must be submitted on your behalf by your institution (usually they are submitted by an Office of Sponsored Programs, but the name will vary from institution to institution). They almost certainly will require you to complete and submit your application to them well in advance of the published receipt date, October 11, 2013.

- Applications **must** be submitted electronically through **www.grants.gov.** There isn't a parallel or shadow system. You can't send a copy of your application, paper or electronic, to Dr. Huntley.

- Make sure that **you and your organization** have completed all of the necessary registrations, including: the System for Award Management (SAM); Grants.gov; and eRA Commons. Applicant institutions are also required to have a Dun and Bradstreet Universal Numbering System (DUNS) number. These registrations can take several weeks to months to complete. Grants.gov will not accept applications from organizations that lack these registrations.

- While someone else will be submitting your application to NIH, it is **your** responsibility as PI to view your application in the eRA Commons before the due date to ensure your application was submitted accurately and successfully. Once the deadline has passed—5 p.m. local time on Friday, October 11, 2013—your application cannot be changed or amended. This means that:
    - 1) you should know what the submitting institution's deadline will be
    - 2) you should make sure that they do not submit your application at the last minute
    - 3) you should **carefully** look over your application in Grants.gov to make sure it's complete and accurate. We all make mistakes; be sure that you have time to catch them.

- Finally, remember that your application will be assessed for responsiveness prior to review; if your application is seen to not respond to the requirements of these RFAs, it may be returned to you unreviewed. We strongly recommend that applicants contact the appropriate program officer (Dr. Kristen Huntley for NCCAM, Dr. Dave Thomas for NIDA, and Dr. Ranjana Banerjea for the VA) prior to submitting their application.

PARTICIPANT'S QUESTIONS AND ANSWERS

QUESTION: Can I e-mail Dr. Huntley directly to determine the feasibility of my project prior to sending a letter of intent or is the letter of intent the first point of contact?

ANSWER: You may contact Dr. Huntley by e-mail prior to sending a letter of intent to discuss the fit of your research concept with the FOA; a letter of intent is requested but not required.

QUESTION: Does each study have to be conducted at the VA setting, or any other setting?

ANSWER: It does not have to be at a particular VA site. An investigator could conduct a study at a community site and recruit veterans to the community site.

QUESTION: Is current funding from NCCAM required?

ANSWER: No. Having a currently funded grant is not required for this funding opportunity announcement.

QUESTION: I serve on a standing study section and have eligibility for continuous submission; would this apply to these FOAs as well?

ANSWER: No, it does not. If you want to submit an application in response to any of these FOAs, you must submit your application by 5 p.m. local time, October 11, 2013. Continuous submission does not apply to RFAs.

QUESTION: How will NCCAM decide if the application goes to the VA, NIDA, or NCCAM? Does it matter?

ANSWER: Prior to review, staff from NCCAM, the VA, and NIDA will meet and indicate applications of interest and discuss nonresponsiveness and responsiveness so that there is some preliminary determination prior to review. Typically, when institutes or centers (ICs) and other agencies collaborate like this, there is some flexibility in the process. In addition, from NIDA's and the VA's perspectives, they will be "pretty flexible" in taking most applications that come in under this.

QUESTION: Can I request assignment to NIDA rather than NCCAM if I feel NIDA may be a better fit?

ANSWER: Yes. You may put that in your cover letter. Typically RFAs are all initially assigned to the issuing IC. Once determinations are made they are transferred to the other ICs or agencies. But you can certainly put that request in your cover letter. It is suggested that you also include some rationale if it is not obvious. Thus, bringing it to our attention might facilitate bringing your application over to the requested assignment.

QUESTION: Do we have to already be an existing part of a VA, or is it expected that we should be working with the VA?

ANSWER: The VA only funds people who are already employed at the VA, or will be employed at the VA as a result of this funding. Write to Ranjana Banerjea, the program contact at the VA listed on the RFA, if you have a more specific question. In addition, there could be a scenario where, for example, an investigator at an academic institution not affiliated with a VA site might propose a study where they are recruiting veterans from the community utilizing means such as newspaper ads in the community newspaper.

QUESTION: Is the VA reviewing the VA applications that come in?

ANSWER: No. The VA is working with NCCAM and NIDA to review the applications and will be involved in the process. These applications are coming to NCCAM. They will be reviewed by a special emphasis review panel that is convened by NCCAM.

QUESTION: I was wondering if it is allowable to submit two proposals as PI or co-PI on both if they're different projects?

ANSWER: Yes, it is permissible. However, sometimes reviewers can raise questions about your ability to manage both projects, and that is something that you would have to address in your application. Additionally, your dual applications would have to be scientifically distinct.

QUESTION: Do you have to have pain as a primary outcome for the R34 opportunity?

ANSWER: Yes, for all three of the funding opportunity announcements, pain or pain management needs to be the primary outcome studied. An R34

could propose to assess acceptability; feasibility of recruitment, randomization, and retention; and adherence to an intervention for an intervention that focuses on pain or pain management as the primary outcome variable. The intervention studied must have pain as the primary focus.

QUESTION: What about a study that is looking at the feasibility of the intervention or recruiting strategies?

ANSWER: That is certainly appropriate for the R34. The outcome measures proposed for the intervention studied in that feasibility study needs to have pain as the primary outcome variable. So Specific Aim 1 would be assessing feasibility, but the primary focus of the intervention studied should be pain or pain management.

QUESTION: My question has to do with the sampling and some of the secondary symptom clusters that might be addressed by an intervention. So if pain and/or pain management are the primary outcome measures and the other areas span PTSD, and TBI, I am wondering about areas such as sleep, anxiety, depression, etc.

ANSWER: Are you looking for a focused symptom population—for instance, pain and TBI, or pain and PTSD? Or would it be appropriate to sample on a broader range? The FOA encourages applications that focus on pain or pain and associated symptoms. It would be up to you to make a strong justification or provide a strong rationale for the groups you are proposing to study.

QUESTION: Often in these populations there is a combination of brain injury and PTSD and difficulty with sleep and potentially over use or misuse of prescription medications. So I will have sample groups that are going to have a number of these symptom clusters, and I am just wondering, especially with regard to power, if there's any advice with regard to this sample and outcomes?

ANSWER: Please feel free to e-mail program contacts with questions specific to your research concept. Encouraging research on pain and symptoms associated with co-morbid conditions stems from conversations with various staff and different organizations from the DoD and the VA where they talk about, and this is true in civilian settings, very rarely do patients come in with one specific diagnosis.

There is a pressing need in these health care systems to have research evidence to inform clinicians regarding what would be helpful for their patients who are presenting with multiple issues. A research priority at NCCAM is the study of complementary approaches for symptom management (such as pain and sleep disturbance), improving quality of life, enhancing coping skills, and improving resilience. These outcome variables are of great interest in the context of managing both pain and other symptoms.

With a power analysis, you will need to work that out to include outcome variables of interest and still have enough power to find significant differences if they exist. We recommend working closely with your biostatistician. It will be up to you to propose a research question, study sample, and outcome variables with sufficient power and rationale to convince reviewers of the merit of the proposed research.

QUESTION: My interventions are not CAM interventions; rather it is a nonpharmacologic one. Is that acceptable?

ANSWER: Interventions that include what would be considered a complementary component, such as yoga, acupuncture, meditation or mindfulness, deep breathing, etc., would be of a higher priority or interest to NCCAM. The FOA specifically allows cognitive behavioral interventions that target both pain and another condition. For NIDA, yes, if you are looking at a certain variation or a change in the way you do cognitive behavioral therapy, or you have something related to that even though that's not typically a complementary health approach, NIDA or VA would probably accept it. But as mentioned earlier, that would probably be a lower priority; we are particularly interested in complementary approaches. But certainly something like virtual reality or magnetic brain stimulation, from the NIDA perspective, would be considered responsive and something NIDA would be interested in.

QUESTION: How many applications do you anticipate will be funded in each one of the three different FOAs? My second question is, in terms of clinical trials and interventional studies versus health services and observational studies, I am not sure that I am clear what the difference between those two categories is, so can you please give us an example of each.

ANSWER: These are great questions; thank you. Five to seven applications will be funded across the three FOAs. The VA is participating only in the

health services FOA, and it is planning to fund one to three applications. This is all the guidance or definition we have at this point.

As to your second question, "What's the difference between a clinical study and an observational study?" In many DoD or VA settings it is not feasible or ethical to conduct a randomized controlled trial. Randomized controlled trials should be submitted to the clinical studies FOA. Observational studies, such as collecting outcomes on particular programs or interventions in practice-based settings should respond to the health services/observational studies FOA. If you have questions about which would be the best fit for a particular application that you are proposing, you can send a one-page research concept with specific aims to Dr. Kristen Huntley if it is relevant to NCCAM; if it's a VA proposal, send it to Dr. Ranjana Banerjea; and if it's a NIDA-relevant question, contact Dr. Dave Thomas. We will take a look at it and provide feedback regarding which FOA would be the best fit.

QUESTION: Can we submit an application as dual assignment to both NCCAM and NIDA?

ANSWER: In your cover letter you could request a primary assignment to one of the NIH ICs, and a secondary assignment to another IC, just as with any other application you submit to NIH. The real advantage of a dual assignment is that multiple people within multiple ICs will see and consider it.

QUESTION: In the letter of intent, should we include a specific aim?

ANSWER: The letters of intent are requested but are not required. In the FOA we are only allowed to request specific information according to NIH guidelines. The letter of intent is requested in order to help with review planning. You could include additional information in a paragraph; that is always helpful. Also, it would be helpful to provide a few sentences to describe the project. That would give us a heads up if something about the application may be heading in a nonresponsive direction or would benefit from feedback to the person submitting the letter of intent.

QUESTION: I have two questions. Question 1: If there are multiple PI options for this, such that one PI could be a VA employee and the other could be a university employee outside the VA, is that permissible?
Question 2: I am a little confused, if the VA is funding only the health studies RFA, and the other two are funded through NCCAM or NIDA

and are also targeting veterans or persons who have or are serving in the military, what is the difference between the VA health services FOA and the other FOAs, beyond who's funding it?

ANSWER: When applications come in, NIDA, NCCAM, and the VA will be looking at them. The VA will be considering only those responding to the Health Services FOA that have a certain budget and time period. If someone proposes research at a VA site, for example, for a 5-year period NIDA or NCCAM would consider that application; NIH funds a lot of VA investigators.

If the research proposed would be conducted at a VA site, certainly there would need to be a VA investigator on the investigative team. The application will need to provide letters from institutional authorities indicating that the study and the investigative team proposed have support and institutional clearance to conduct research at that site. The team would need to be able to get appropriate IRB approvals and institutional approvals, and the appropriate approval to conduct the research at that setting. The other thing I would like to add to that is that it is really up to you which mechanism you apply to. This funding initiative as a whole has three FOAs for similar topics but they are a little bit different. One is clinical, one is health services, and one is R34, which is more of a smaller pilot study. So it is really up to you and the scope of your study, which one you would apply to. The VA is participating in only the health services and observational studies FOA. In terms of the population or the cohort, all three FOAs are looking at similar cohorts. There is no difference on that aspect.

QUESTION: Sounds like someone can submit health services studies that are 5 years long, or one that's 3 years long.

ANSWER: Correct.

QUESTION: It sounds like there is not a requirement for the employment? Assuming that any of the other two mechanisms would of course have investigators within the VA. It sounds like could you have, for example, a PI that's not a VA employee, and other VA investigators?

ANSWER: Yes. The VA is not participating in the other two. VA requirements don't apply there. If you're applying for RFA-AT-14-003, the clinical trials R01, or the RFA-AT-14-004 and the R34, none of the PIs need to be VA employees if you are proposing research to be conducted in a community setting. The research does not need to be performed at a VA or DoD facility. However, the study population has to include

veterans or active duty or reserve personnel and/or their families. If the research proposed is to be conducted in a VA setting there should be a VA employee involved and any investigators with academic affiliations should look into what would be needed by the VA site for their involvement in the research at that site. The VA site would need to determine if they would allow the conduct of the research at their site. Different arrangements are made locally by different VA centers. A letter of support from the local VA Research and Development office outlining eligibility and permission to conduct the research should be included with all applications. Please contact a program officer if you have additional questions.

QUESTION: I am a DoD employee working at a DoD clinical site that treats pain with CAM modalities. My question is regarding the application. Our interest in applying is that there is an academic institution that has researchers who are better able to synthesize the information that we are gathering, and we would like to have enough funds to be able to allow them to be able to participate in helping us. Now should the application be made in our name, in the DoD name, or should it be made by the academic institution?

ANSWER: That is really up to you. Keep in mind that one of the review criteria is environment, and reviewers will be looking at the institutional resources, research infrastructure, etc., of the applicant institution and the other involved institutions. So that is really a decision for your investigative team to make. If the application comes from the DoD, then you are going to need to have all of those institutional requirements, and registrations have to be completed. Applicants have to be registered in the System for Award Management (SAM), in Grants.gov; both you yourself and your institution would have to be registered in the ERA Commons; and your site would have to have a DUNS number. All of these can take time to obtain. Alternatively, you can state in your application that you are going to incorporate the best components of your DoD site and its staff, as well as the university site and its staff. The applicant could make that case in the application. NIH receives applications via the Henry M. Jackson Foundation or other nonprofit entities that have institutional research capacities that many DoD investigators work with. If you need more specific information, you can e-mail Dr. Huntley.

QUESTION: My question was about preference for veterans. Is there a preference for veterans from the current theaters from Afghanistan and Iraq, or—in the criteria, or is it just that that was part of the description trying to get us to think broadly?

ANSWER: Their preference in terms of application funding is not part of this FOA. This FOA does state that there is special interest in research on veterans from these recent efforts but research on all veterans is of interest.

QUESTION: I was wondering if either NIDA or NCCAM would be interested in spirituality-based interventions.

ANSWER: Sure. The applicant would have to make a scientific basis for it, but NIDA is interested in anything that can get people off of addictive pain medications and impact their pain. Therefore, from a NIDA perspective, that is fine.

For NCCAM, the guidance we give is that you would need to be sure to include a strong rationale and/or conceptual model in your application addressing how or why an approach may work, as well as some evidence in the published literature that there is a strong signal, or very strong preliminary or pilot data to support an application.

Scientific/Research Contact(s)

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