DCRC Informational Teleconference Transcript
May 17, 2007

I want to thank you all for your participation in today's teleconference.

The purpose of today's teleconference is to summarize the Developmental Centers for Research on CAM Phase I initiative.

To briefly outline this afternoon's agenda…

I'm going to start by outlining the DCRC I objectives, the parameters and requirements of the initiative, the application requirements, and then Dr. Birkle, of NCCAM's Review staff will describe the review criteria for the DCRC I.

We will take questions at the end of the presentation.

Because of the very gratifying, but unexpectedly large number of people who registered for the teleconference, we ask that if at all possible, you submit your questions by email to (nccamdcrcinfo@mail.nih.gov).

If you don't have access to email, we will try to take some questions over the phone. Certainly we will take follow-up questions to those questions that we received by email to answer over the phone as part of the phone conference.

I will, as coordinator for the DCRC program, continue to respond to questions you have regarding the initiative by phone and email after the teleconference.

I want to start talking about the DCRC I funding opportunity announcement by saying that I hope that all of you have read the text of the FOA, Funding Opportunity Announcement. It is accessible from the NCCAM Web site. The URL for the NCCAM Web site is nccam.nih.gov.

NCCAM research web information

Also on the NCCAM Web site, at the research page, you'll find a lot of information that I think will be very useful, both to those of you who are NIH grant application-experienced and those of you who are not. You'll find the links that will give you access to NCCAM's current research portfolio and the awards that NCCAM is currently funding, information on NCCAM Program staff, information on grantsmanship.

There is a sample funded grant application that will give you a sense of the level of detail and backup information that the peer reviewers will expect to see, information on what NCCAM expects to see in a clinical research application, as well as information on NCCAM's policy on biologically active agents.

Contacting NCCAM Program Staff

Before I dive into the specifics of the DCRC I FOA, if there's anyone participating in this phone call, who's planning to submit an application for August 13 of this year and has not yet discussed their application with a member of NCCAM's Program staff, I strongly advise you and your colleagues to set up that conversation as soon as possible.

NCCAM Program staff in the research areas in which you're planning to focus your application can answer your questions about whether the research that you're planning to propose is consistent with NCCAM's portfolio, NCCAM's research purview, NCCAM's research interests, as well as whether it's substantially similar to research that is already in progress.

NCCAM could not fund a project that was really very similar to something that we are already funding unless (the projects) were in some way complementary (to each other).
Also on NCCAM's research Web page, you will find a list of NCCAM Program staff with the research areas that they oversee and their contact information.

For questions about the requirements of the DCRC I FOA, please contact me, but for questions about particular/specific research areas, please contact the appropriate NCCAM program officer.

If you're planning an application that will focus on cancer that is my portfolio and you'll contact me for cancer-specific questions (as well as for questions about the DCRC FOA)

Developmental Centers for Research on CAM: Phase I Funding Opportunity Announcement (DCRC I FOA)

Purpose of the DCRC I - is threefold; to promote the development of CAM research expertise and infrastructure, to support developmental research projects and to support enhanced communication and partnership building between CAM and conventional institutions and researchers.

In order to meet these objectives, each DCRC I application must include at least one CAM institution and at least one conventional biomedical research-intensive institution.

One of the things that you'll find in the text of the FOA is definitions of CAM institutions and of biomedical research-intensive institutions, the operational definitions for the purposes of the DCRC program.

Very briefly, an eligible CAM institution for the purposes of the DCRC the applicant must be a domestic institution. The CAM institution must have as its primary focus education unique to the CAM practitioners and the students must receive a nationally or regionally accredited (unintelligible) for certification (unintelligible).

For the purposes of the DCRC program, osteopathic research institutions can partner with an allopathic institution, that is they may be considered CAM institutions for the purposes of the DCRC program.

For the DCRC, an eligible conventional biomedical research-intensive institution is an academic healthcare and/or research institution that does not have as its primary goal training of CAM practitioners and that does have a history of successfully competing for biomedical or behavioral research funding.

For the DCRC programs a history of successfully competing for biomedical or behavioral research funding is operationally defined as the institution receiving at least $10 million annually in NIH funding.

Structure of the DCRC

Each DCRC must have an administrative core and three or four exploratory/developmental research projects in each year after the first year.

Each of the three or four research projects must have a leader and a co-leader and one of those must be at a participating CAM institution and the other must be at a participating biomedical research-intensive institution, again, as defined for the purposes of the DCRC program.

After the preparatory/planning year, project leaders and co-leaders and core leaders are required to dedicate at least 15% effort to the project (or core) that they'll lead.

Each DCRC must have an internal steering committee and external advisory committee. In your application, you should describe the organization of the internal steering committee for the DCRC you're proposing. Please do not name specific members of your proposed external advisory committee. If you wish to name the appropriate areas of expertise for your external advisory committee, that's fine but please do not name specific individuals.

The DCRC preparatory/planning year

The preparatory/planning year may be used for recruitment or training of additional administrative staff, development (unintelligible), human subjects training for (unintelligible) subject to research, refining your research plans, purchase installation and requirements of equipments that will be required for the proposed research, development of data collection and verification mechanisms, preparation of detailed protocols, manualizing interventions, developing consent forms, case report forms, obtaining IRB approvals, assembling and submitting to the FDA an investigated new drug application (IND), if you're going to need one for your research.
So that if you're approved to go on to year two of your proposed DCRC, you're really ready to start the research right away.

We do require that anyone who is requesting NCCAM funding for human subjects research with a natural product or other bioactive agent ask the Food and Drug Administration (FDA) whether the FDA will accept an IND application for that research. This is true even if you're using a natural product that is covered under the Dietary Supplement Health and Education Act.

The reason that we've included the preparatory/planning year in the DCRC is that when we first issued the DCRC initiative back in December, 2002, we found that the awardees from those first DCRC awards, as the initiative was originally structured, often spent much of their first award year doing the kinds of things I've described; obtaining IRB approvals, setting up administrative

procedures…And as a result they didn't use up that much funding because they weren't ready yet to start doing (the) research, but they were (still) burning through part of their award time.

So we (felt) that was what was needed was to award the funding for you to get started on those preparatory activities.

At the end of the preparatory planning year, probably nine months after the award date, there will be a programmatic review of each DCRC that will evaluate the extent to which the objective that you've proposed for the preparatory planning year were achieved. Continuation of the award for years 2 and onwards will be dependent on that programmatic review. There will not be a new application required for continuation, just the progress report and review of the preparatory/planning year.

DCRC structure: budget

You're allowed up to $100,000 direct costs for that preparatory/planning year that I was talking about.

For multi-institutional applications that will include the direct cost of subcontracts but that $100,000 doest not include indirect costs, (that is) facilities and administrative costs on the subcontract.

If the award continues, for the years beyond the planning phase, you're allowed up to $600,000 per year in direct costs. And again, that includes direct costs on subcontracts, but not indirect costs on the subcontracts.

As you'll see in the key information for the funding opportunity, DCRC I awards as well as DCRC II awards will be funded through NIH's U19 mechanism. The U19 is a cooperative agreement mechanism, which means that DCRC awards involve substantial participation of NCCAM program staff and the details of that participation and the interaction between NIH staff and research staff of the participating awardee institutions are detailed in the text of the funding opportunity announcement - towards the end.

I talked a little bit about percent effort requirements for Program Directors/Principal Investigators (PD?PIs). In the preparatory planning year, each PD/PI must commit at least 10% effort.

The DCRC program accepts multiple PI applications. If you're submitting a multiple PI application for the DCRC, each PD/PI must commit at least 10% effort during the preparatory planning year.

For years 2 through 4 of the DCRC, each PD/PI must commit at least 30% effort, and that must include at least 15% effort to the administrative core or another core and at least 15% effort on one of the research projects.

Format of the application

Letters of intent for DCRC applications are due July 13 of this year. If you are planning to submit a DCRC application, please do send a letter of intent.

Letters of intent help NCCAM's review staff to get your applications reviewed in a timely fashion and by optimal reviewers. In order to help them do that, please include in your letters of intent a paragraph or two describing each project or core so that they can begin to plan for the peer review.

The letters of intent does not commit you to submit an application on August 13 and you're not required to submit a letter of intent in order to submit an application.

DCRC applications must be submitted and received on paper in hard copy. Although the NIH and NCCAM are transitioning to electronic applications, the U19 cooperative agreement mechanism has not yet made that transition.

So these applications will need to be hard copy and they will need to follow the instructions in the funding opportunity announcement as to the number of copies, where to send those copies, and when they need to be received. And they need to be received on or before August 13 of this year on the PHS 398 forms.

You can access the PHS 398 forms that you'll need to use for these applications from NCCAM's research Web page (http://nccam.nih.gov/research/) The current version of the form, and please make sure that you are using the current version, is dated April of 2006 or 4/2006.

There are a number of other submission requirements that you'll see in Section IV.6 of the funding opportunity announcement.

Some of the issues that you must cover in the DCRC application are, how the different components of the DCRC that you're proposing will interact, why they're essential to accomplishing the overall goals of research, how the combined resources create capabilities that scientifically informed and enhance each other. You'll need to describe the collaborative process and methods of communication between the different DCRC components, especially the case where component institutions are geographically or physically separated. In such cases, address specifically how you're going to manage communication across the distance, how often, for example, you're going to use teleconference, video conference, travel between sites to have face-to-face meetings. And of cores, if you're planning to travel, you're going to need to include that in your budgets; similarly for video conferencing activities.

You need to describe in your application how the different collaborating institutions are going to achieve the goals of developing research infrastructure at the participating CAM institutions and in developing competitive projects and preliminary research results to support later applications to futher CAM research and support it at the CAM research institutions and at the conventional biomedical research-intensive institutions.

You'll need to show that the research projects that you're proposing constitute new research activities; that they are substantially different from anything that's currently funded by NCCAM.

That doesn't mean that you can't propose another chiropractic center just because there's already a DCRC that focuses on chiropractic. But any new application should be significantly different from the current NCCAM-funded chiropractic Developmental Center.

You should make sure that you're including in your application letters of support from the appropriate official at each participating institution. And those letters should document the institutional commitment to the DCRC and to the collaboration as well as each partner's expectations for interactions and performance on their part, as well as their expectations of the other participant(s

And for the participating CAM institutions, you must include documentation that they are qualified to participate in the DCRC.

For all DCRC applications:one, institution must be the lead or applicant institution on each application.

The other participating institutions will be submitted as subcontracts to the lead institution.

The actual format of the application will be a series of sections and each of those sections will look essentially like a research project application for an NIH RO1 or developmental/exploratory (R21) grant. You will need to coordinate those sections so that they're consistent and unified.

The first of the sections will be the overview section. The overview section will address the overall objectives of the multi-project DCRC; the relationships among the different research projects, the administrative structure, including the administrative core; the multi-PD/PI leadership plan if you're planning to submit a multiple PD/PI application, and.any scientific cores that you plan to have. Explain in the overview section how each component will contribute to the overall objectives and to the overall budget for the DCRC. It would be good to include in your overview section a timeline with the objectives for the preparatory/planning year and what you expect to accomplish in the other years that you're asking for funding for. Any cores that are included other than the Administrative Core should be utilized by at least two research projects. The Administrative Core should serve all of the research projects and cores that you're proposing.

The overview section should include, in Part J of the research plan, letters on institutional letterhead from the various participating institutions indicating their support, as well as letters from each PI and each project or core Leader or Co-Lleader confirming their support and their role on each project or core. It also may be critical to include letters of support from any consultants who are going to play key roles in your DCRC or its component research projects or cores.

Multiple PD/PI applications

One person - one PD or PI must be designated as the contact /PDPI. The contact PD/PI must have an appointment at the lead institution ()the applicant institution and that contact PDPI will be responsible for all NIH contacts, including submission of the application and progress reports and will be the point of contact for all NIH communications.

On Form Page 1, the face page, of your application, for multiple PD/ PI applications, put the contact PI's name on that page, in Section 3. For multiple PD/PI applications and only for multiple PD/PI applications, you must also include the Form Page 1 continuation page and on that page you include all Program Directors/Principal Investigators; not other personnel but just all PDs/PIs for the application. The contact PD/PI should be listed first on the Form Page 1 continuation page.

On Form Page 2for the overview section of the application, list all key personnel for the DCRC, including those for all the projects and all the cores together. This complete list of key

personnel, will extend beyond the PDs/PIs, and must include all project Leaders, Co-leaders, Core Leaders and all other key personnel.

It is also welcome if you list the key personnel for each individual project and core in the relevant section of the application, but that initial list of key personnel in the overview section is very helpful.

For the overview section and for each subsequent section of the application, you also need to include the PHS 398 forms, Form Pages 4 and 5 for each participating institutions. Form Page 5 is the budget for the years beyond the preparatory/planning year. When you are preparing this application, you will need to have thought through, in a fair bit of detail, the research that you are proposing for the years beyond the preparatory/planning year.

You need to describe in the overview section of the application your preparatory/planning year activities, how they'll be conducted, how communication and planning will be done, how the preparatory/planning activities will contribute to the success of the proposed DCRC I research projects and to enhancing the ability of the participating CAM institutions to independently obtain additional CAM research funding as the award goes on and how the DCRC I and the preparatory planning year activities will contribute to building ongoing collaborative CAM research.

Providing a time-line for completion of activities and achievement of objectives/planning year and in later years of the award is very helpful.

Multiple PD/PI applications must include in the overview section the leadership plans, which need to detail now the responsibility for leadership will be allocated and coordinated between the PD/PIs. The leadership plan should describe the roles and responsibilities each PD/PI will have, how decisions will be made on scientific direction, resource allocation and how any disputes that may arise will be resolved.

For the overview section of the application, Sections A through D of the research plan are limited to 25 pages.

Following the overview section, include a section in the application for each individual research project and each core that will be proposed.

Again, for each research project (or core) section include a PHS 398 cover page for each participating institution, as well as budget pages for each participating institution.

The application should be paginated as a single document with one appendix at the end of the entire document and preceding that appendix, biosketches for key personnel for all projects and cores as well as for consultants.

Where there are no specific instructions for the application in the FOA, please follow the PHS 398 instruction.

Noncompliant applications may be returned without review as being non-responsive.

I have a question that has come in: "Will the DCRC Phase I be accepting applications, again, in 2008?"

The answer to that is that I hope so, but I cannot promise that that will be the case. At the moment, the DCRC I FOA is issued only for 2007.

Review Criteria for DCRC I Applications (Dr. Dale Birkle, presenter)

There are multiple components to the DCRC application.

Some of these components are reviewed in a standard way using the five standard NIH review criteria. These components receive a numerical. Other components are reviewed based on the review criteria in the funding announcement and they receive what we call merit descriptors; outstanding, acceptable or unacceptable are the three merit descriptors.

Reviewers are asked to comment on each of the principal investigators(PDs/PIs). This doesn't actually receive a merit descriptor but there are reviewers looking at the qualifications of the PDs/PIs.

If it's a multi-PD/PI application, then of course, all of the PDs/PIs are reviewed and each PD/PI should be someone who can take over running the project, someone who has a strong track record in managing complex projects.

In other words, the philosophy behind the multiple-PI scenario is that any of those people could be PI on their own. Any of the PIs would be able to fulfill all the requirements that one would expect of someone leading a project.

Barbara has mentioned the leadership plan, which is written in the overview section of the application. The leadership plan describes how the different parts of the DCRC will collaborate and communicate with each other and how the PIs will coordinate with each other in leading the DCRC.

The Leadership Plan should be quite detailed in explaining how meetings will be conducted, how often etc. There's a link from the FOA to the (NIH) multi-PI Web page. That page gives examples of leadership plans for all kinds of different mechanisms including multiple component mechanisms like the U19 and it would be good to look at that so that you are sure to cover everything. For example, things that should be discussed in the leadership plan include how credit is going to be divvied up for publications and things like that, how money is going to be managed, who's going to be responsible for making decisions about how the grant funds are distributed among the different components. The leadership plan actually asks the applicants to really think about how this is all going to work.

Multiple component applications like this one is the kind of thing that NIH were thinking about when it instituted the multi-PI application. It lends itself quite well since you have two or more different organizations collaborating together. For example, if your personnel fit the criteria then, you know, you could have a PI from each of those institutions.

The leadership plan is written in the overview section of the grant. It's evaluated as part of the resources and environment section of the application.

The reviewers' scores for the individual research projects and cores are major contributors to the final score for the DCRC; the individual research projects will be evaluated essentially as exploratory/ developmental projects, like R21 applications, and they will be scored on the basis of the five review criteria that NIH uses for all applications; the scientific approach, the environment(s) for that particular project, the investigators and other personnel, and the innovation.

How the Final Priority Scores for DCRC Applications Are Determined (Martina Schmidt)

I have been running the DCRC review meetings and I thought as part of the teleconference it would be important for all of you to know what is actually happening during the review of these applications.. For the DCRC I applications, we start out talking about the preparatory/planning year and then we talk about all your projects then we go through the cores and then we look at the other additional review aspects.
During the meeting we have a big flip chart that is visible to all the reviewers sitting in the room and we record the numerical scores of the assigned reviewers. We calculate the average score that has been given by the assigned reviewers for each of the research projects, and then based on that, we calculate the average score for all the projects together.

For the additional review aspects (the cores, the resources and environment, and everything else that we have just talked about) we ask the reviewers to let us know if they feel the additional aspect is outstanding, acceptable, or unacceptable; we do this by hand count.

Core A, for example, might get 18 votes for outstanding, and 5 for acceptable.

We ask the reviewers to look at the average numerical scores in combination with the additional aspects to arrive at their final overall scores. If the Cores and the additional aspects in general are outstanding, then their overall score should be better than the numerical average, meaning a lower number than the average score for all your projects,, or vice versa if they think that the cores and the addition aspects are not that good, then the overall score should be a higher number, in other words not as good as the average score for all the projects.

I really want to stress that if your resources and environment, for example, the proposed interactions between the participating institutions, are perceived to be suboptimal, it's considered that this would influence your ability to really do your project, and that will have a significant influence on your final score. So these aspects should be carefully considered while preparing the application. Also, keep in mind that the additional aspects can influence your final, cumulative score in either direction. For example, if there's an issue with one of your projects; this can be counterbalanced if everything else around it is just great,.

Q&A

Question: Other than the 10% effort required from the DCRC I PI and any co-PIs, are there criteria to guide the percent efforts for the project co-leaders during the preparatory/planning year?"

Answer: The only thing that should guide your determination of the effort of the other participants in the preparatory/planning year is rationale; what makes sense, how much effort is really needed, what the competing demands are on the limited budget available, and what is needed to achieve the objectives that you proposed for the preparatory/planning year.

You might want to have somebody who's actually on the administrative stuff or of one or more of the participating institutions on budget for some percent effort in that year if you are working on putting together an IRB at an institution that doesn't have one, for example, or developing an indirect cost proposal, if you have a participating institution that doesn't yet have a facilities and administrative (F&A) agreement with DHHS.

Question: If an institution doesn't have a policy on intellectual property rights, would that mean that an application from that institution would be rejected.

Answer: No, it wouldn't be rejected. If you're in the process of submitting funding applications, that's something you should definitely work on. By the time we were ready to make an award we would certainly want you to have that.

But that (IP policy) should not be necessary for you to begin preparing an application.

Question: Are the Co-leaders considered to be co-PIs on individual research projects? Do you need a Co-PI continuation page for research projects that have Co-PIs?
Answer: I think I need to clarify nomenclature. The overall DCRC has one PD/PI or multiple PD/PIs so that for the overall DCRC application, you may need a continuation page for co-PDs/PIs.

The individual research projects have Leaders and Co-Leaders. That's not the same thing as a Principal Investigator. So if a project has a Leader and a Co-Leader, as is required by the DCRC FOAs, you just list all the personnel (including the Leader and Co-Leader) for the project in the list of key personnel in the Overview section of the application (indicating that they're Leader and Co-Leader, of, let's say, Project 2), and it's nice to also list them in the section of the application for that research project.
NIH is trying to move away from the use of the term "co-PI" because, I guess, they want all PIs to be created equal. So they talk about multiple PIs or about projects having two, three, four PIs and they're all called PIs now.
For the research projects, those are project Leaders and there can be more than one project Leader.
In fact, the DCRC FOA requires that each research project have a Leader and Co-Leader, one each from a CAM and from a conventional biomedical research-intensive institution.
But that's not the same thing as multiple PDs/PIs. So you don't have to write an elaborate leadership plan for those Co-Leaders. In the budget justification or personnel justification section, you should talk about what the role of each person is going to be.

Definitions:

IRB	An IRB is an Institutional Review Board. If you are performing research with human subjects, that research must be approved by an Institutional Review Board before it can be funded by the NIH.
IND	An IND is an Investigational New Drug application. It may be required for a natural product study with human subjects that involves ingestion or application of the natural product by the human subjects.