

The 2013 CCSG Guidelines: Objectives, Themes, and Changes

Moderator: Shannon Silkensen
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Operator: Welcome and thank you for standing by. At this time all participants' lines will remain on a listen only mode. Today's conference is being recorded. If you have any objections you may disconnect at this time.

I would like to turn today's call over to Dr. Shannon Silkensen. Ma'am, you may begin.

Shannon Silkensen: Thank you so much, Sandy. Hi, all. My name is Shannon Silkensen and I'm a Program Officer at the NCI's Office of Cancer Centers. We're excited that you all are joining us today for discussion about the objectives, themes and changes to the CCSG guidelines. Today we are joined by a woman who needs no introduction to this audience: Dr. Linda Weiss, the Director of the NCI's Office of Cancer Centers.

However before we begin, I must go over a few housekeeping details with you. To see the slides you'll need to have Microsoft Live Meeting installed on your computer. This works best if you close all other applications. You will hear the audio portion of this presentation through the telephone at the number listed on the webinar invitation. Unfortunately, you cannot hear it through your computer.

To ask a question, please use the Q&A box at the top of your screen. You may type the question in at any time during the presentation and we'll do our best to answer them at the end.

At this point I'd like to turn the presentation over to Dr. Linda Weiss and she will begin.

Linda Weiss: Hi everyone, and welcome to the webinar on the 2013 CCSG Guidelines. The purpose of this Webinar is to brief you on the new guidelines and to respond to any initial questions that you may have. I say initial because I'm aware that questions may develop as we move forward. I'm going to do a short slide presentation today, walk you through a few of the common questions that we have already received in regard to the guidelines, and then we'll respond to questions from the Webinar participants.

But before I begin I just want to mention a few things. First, for those of you who are not aware - and I realize we may have existing cancer centers, emerging cancer centers, and others on the line - the program announcements, the guidelines, the list of changes to the guidelines, and the FAQs are all on our website and the Web address is on the first slide that you see in front of you. We will be adding to the FAQs on a regular basis so you may want to check those periodically for additional or new information. Also if there are questions today that we can't answer for one reason or another, we will post the answers on the FAQ list and we'll let you know when that happens.

Second as you prepare a competing application, we suggest strongly that you use the guidelines as your primary resource rather than the funding opportunity announcement because the guidelines have greater detail in them. And third, today's presentation I want to remind you is going to focus on the main guidelines, the data tables - which many of you know more fondly as the

summaries - are going to be discussed in a follow up webinar scheduled for November 15th from 2:00 to 3:30 Eastern Standard Time.

So rather than walk through the guidelines by individual section today I am going to focus on the major themes that cross multiple components. I'm then going to discuss briefly a few other changes in project and application requirements, walk you through some of the modifications in the review process and procedures, and then as I mentioned, end with some of the questions we have received in follow up to a presentation that I did at the Association of American Cancer Institutes meeting a couple of weeks ago.

So the first theme I want to focus on is strengthening the focus on the quality of science. Although we in the program firmly believe that under the former guidelines, quality of the science was the major driver of the impact priority score along with the six essential characteristics, we agreed with many of you that there were other requirements, sometimes of much lesser relevance and importance, that often consumed an inordinate amount of time for the applicants and reviewers. And the revisions that we've made in the 2013 guidelines place a much greater emphasis in both the narratives and the review criteria on the scientific importance and impact of practice changing research.

At the same time we tried to reduce some of those more burdensome and irrelevant requirements and the detailed shared usage tables that many of you have submitted for decades probably is one great example of this. Now, we are trying to emphasize the strategic value of the shared resource to the science at the center.

In clinical and translational programs, we're trying to take the focus off accrual as a primary metric. That doesn't really make a lot of sense in the clinical trials environment anyway. And again, focus more upon the quality of

the trial. We are also looking at how the investigator initiated trials, capitalize and build upon the scientific strengths of the center.

In the new guidelines we have strengthened the accountability of the director and the senior leadership in regard to establishing scientific direction, priorities, and strategies for the Cancer Center. And finally we have tried to clarify and strengthen the language in regard to consortium arrangement and what our expectations are in terms of the research strengths all consortium partners bring to the table.

So the second theme is focused on emphasizing harmonization and collaboration. As many of you know we have historically focused on collaboration within the cancer center. Many of you have rightly pointed out that it is not really possible for a cancer center to carry forward a finding from bench to bedside in isolation. Centers clearly need and want to collaborate with each other and with other partners in research. They also want to share resources. And on the NCI side, the clinic trials advisory working group identified a lack of collaboration and coordination among NCI programs as well.

So in the proposed revision, we've tried to really address both of these issues to ensure that centers receive recognition for a spectrum of collaborative efforts that involve coordination across NCI mechanisms and collaborations with other kinds of external partners: cancer centers, other institutions, industry, whatever advances the scientific goals of the center. We've also allowed the sharing of resources across cancer centers through the developmental funds components.

We have specifically incorporated language which now recognizes leadership and participation in national clinic trials network trials which was not

specifically in there previously. We have standardized some of our summary data definitions with CTRP. We'll talk more about that in the webinar on the 15th. And we've tried to enhance the standing of team science and clinical staff in the institution both through some requirements related to institutional promotion and tenure policies and through clearer language that encourages research program membership for a clinic staff.

In addition to that, we now have the possibility for a global health project to be supported through both developmental funds and early phase clinical research support. And we now recognize participation in trials involving rare cancer centers. In fact we're encouraging cancer centers to participate in these types of trials.

The third theme is facilitating clinical and translational research. This comes from the discussions that we've had over the last few years with numerous clinically oriented staff and cancer centers. They've uniformly identified a concern with a level of support for clinical and translational infrastructure in the guidelines and also with outdated and complex data requirements.

So to some degree I think this had to do with the way in which some of these components were structured. So what we started with was pulling the clinical data management system - what some of you more appropriately think of as the clinic trials office - out of the shared resource component and making it a separate component. This allows both greater flexibility in terms of the way in which you use the resource, and it allows us to structure review criteria that are more appropriate for this particular component of the application.

We've also made some changes to the PRMS, which encourage processes that assess and foster efficiency: for example two-stage reviews, limiting full review to institutional and industry trials. I want to emphasize the word

encouragement here. These are not requirements but we are trying and keeping with the Clinical Trials Advisory Committee recommendations to foster better, speedier trial completion.

We have expanded use of funds for early-stage clinical research activities. This used to be the protocol specific research support components. And in essence, what types of study you support here hasn't changed, but the ways in which you can use funds to support these early phase studies has expanded considerably.

We tried to simplify quite a few of the reporting tables that I think probably served no useful purpose for either program or review staff. And again we've recognized some of the unique accrual issues in trials of rare cancers and targeted therapies.

The fourth theme is aligning stage two requirements for comprehensiveness with those of the cancer center support grant's, objectives and center scientific goals. And I've mentioned I think in other presentations - and as many of you know this has traditionally been a two-stage review with the first stage review focusing on scientific requirements and the second stage review focusing on outreach and education in the community. Over the course of time we've realized that when you do a second stage review sometimes even a year after the first stage review you really lose a lot of the context that you had in the original application. We also found that the quality of the second stage applications varied widely, and that the approach and review - although we've changed that approach several times - continued to be somewhat problematic. We've tried several different ways of reviewing the second stage and just decided that none of them were proving very effective.

So, what we are proposing in the new guidelines is a one-stage review. This one-stage review will take place at the Parent or NCI-A meeting at the same time the primary application is scored. As before, the breadth and depth of research across the three major scientific areas as well as the trans-disciplinary research bridging them will be major considerations. This aspect of the review has not changed. But since we, and actually the U.S. Congress, also had a great interest in the education, training, and service to the catchment areas of the NCI-designated cancer centers, we've now incorporated those into the one-stage review as well with the criteria now focused on how these efforts integrate with and enhance the research of the center.

There is no separate written section for the comprehensiveness review. Instead, as before, the comprehensiveness elements are imbedded into the existing, relevant components of the application and, this slides shows where the education and training, and service in the catchment area components are embedded. I won't go through them right now.

But I want to mention that this is a changing in review. It isn't our intentions to either make it more difficult or to make it easier to gain the comprehensive designation. But, to really to place training and service into the larger research concept of the cancer center and to make the requirements a bit more consistent with the purpose of this grant, and to address ongoing issues in the application and review process. I guess I would also say that we think this will ultimately reduce the burden on the cancer center as well since in the prior approach you had to submit the separate 25-page application with brochures and other materials. Also I want to just emphasize that it's not our intent with this change to imply that actual service and outreach within the community setting and education in the communication are not important because we really think they're going to be necessary to foster the trust and involvement of the community in research and other activities.

So I want to spend a few moments on some other issues: eligibility to apply, budget request, and funding. I think that a number of you have heard some of this material before but for those of you who are new, I'll repeat it again.

The former \$4 million eligibility requirement for cancer related funding was initially established to allow application from smaller centers. As time has gone on, it has become obvious to us that an application that has only a \$4 million minimum direct cost cancer relevant funding level will not be competitive in review. It's virtually impossible to assemble a critical mass of research and three vibrant programs with that level of funding. So as a consequence we're proposing raising that minimum to \$10 million in direct costs. I want to point out that this is not just NCI funding. This is NCI, it's NIH, it's funding streaming from the peer-approved organizations that are listed on our website.

Clearly though, our investment - our major investment at least - isn't really in the funding of new centers but in our existing cancer center pool; those competing and non-competing centers. We've eliminated the benchmark ratio which really didn't serve the interests of any of the cancer centers in the portfolio. But, we still face the problem - right now at least - of some fairly serious financial constraints. Realistically, we anticipate the budget for centers to remain relatively flat over the over the foreseeable future. In fact, I could probably remove the word relatively there and just say flat. So we're proposing an approach to budget requests for re-competing centers that reflect that reality.

So as we expect no major influx of new funds, we've developed the guidance that you see here. Applications that have an existing award equal to or greater than \$6 million in direct costs will be capped as their current direct cost level,

and this is in terms of the budget request that you submit any application. Applications below that \$6 million direct cost level will be capped at a total direct cost budget of \$1.0 million or 10% above the direct cost level of the last year of their non-competing project period, whichever is greater. And I want to clarify this with an example. If you are a center that currently has a direct cost award on say \$700,000, you would probably want to request \$1.0 million in total direct costs. If you are a center - on the other hand - with a \$3 million direct cost award, the - what you could request is 10% above that which is \$3.3 million.

Requests for larger budget increases will only be considered under specified circumstances and after consultation with program staff. And as of now the only specified circumstance that we are encountering in terms of these are those requests from centers that are either on unfunded extensions or extreme diet funding of 50% or less than their prior award.

We realize this is not a happy scenario for anyone, but it does allow the centers to set some realistic expectations at the time of application, and it allows the peers to predicate their assessments of merit and future accomplishment on what is actually a tenable budget request.

I'll be very brief with this slide. We were trying to reduce the burden of the application. I expect we'll continue to work on that over time. What we've done to date is eliminate I think a number of redundancies across components. We have eliminated the indigent capacity tables and the shared resources. Everyone seems to be pretty happy about that. Requirements for meeting agendas and other data that were not quite so consequential to review. And in the clinical components, as already noted, we tried to simplify the data tables.

So I'll close with some changes in review process and procedure and then go to some comments/questions. As you know effective with the 2004 guidelines, we implemented an option known as the limited site visits option. This option involved an application, a shortened site visit timeframe, and the appearance of the director and the administrator at the parent committee review of the application. This was in place of application and full site visit. That option was never broadly used and over time, I think we've found that the cost benefit ratio is it's not really in our favor. It was still expensive for the center and the NCI in terms of site visits and trips and probably added minimal value or change to the outcome of the review.

So what we have done now is created an application-only option. I want to emphasize that this is truly application only; there is no site visit of any kind. It's a written application and I believe I've used the term like an R01 application. If you want to avail yourself of this option that's really what it will be like.

We have also tried to change some of the site visit logistics. What we really want to do is try to focus review site visit time particularly on updates to the paper application you already submitted. And, to allow reviewers to get clarification and ask questions and get responses from the grantee. So under the current guidelines, a site visit will usually be about a maximum of five hours onsite. That excludes breakfast for those of you who have asked this question. It does not exclude lunch because there is an executive session that the site visit team has during the lunch period. The actual timeframe - and some of you asked about this - will be decided in consultation with the scientific review officer.

In the course of the site visit, we will be allotting 30 minutes for shared resources - which you can use for either a poster session and/or a Q&A with

your leaders. A poster session though, is optional. It is no longer required. So it's up to you as to whether you present poster session or not.

Review of the shared resources will be based primarily on the paper application plus site visits updates - or updates at the site visit. This might be in the slide book. If you want to do posters, if you want to do it in a Q&A, again we're really looking to see what's changed in terms of technologies or leadership since the paper application was submitted.

And the other change in the shared resources is that they will be voted on by group and not individually. And I'll return to that in a moment when we get to the common questions.

So these are some questions that we have received since I spoke at the AACI meeting. We thought to sort of “prime the pump” we would start out by addressing a few of these in the webinar today. Some of these centered on research in the catchment area, on review, a few questions about budgets, and I'm sure you'll have others once we've gone through these.

So one question related to how is the catchment area defined? You actually have been defining the catchment area in all of your prior applications in the section on accrual of minorities and women. We've provided a little bit more specific definition to guide you in how you define that in the new guidelines, but it still ultimately will be determined by you. It has to be population-based using census tracts, zip codes, county or state lines, or other geographically defined boundaries, and it has to include the local area surrounding the cancer center. But beyond that, you will determine what it is and you will justify your selection.

The second question was what might be included in research in the catchment area? And I want to give you just a few examples. Certainly this would include research focusing on health disparities. This is actually very broad. There is a definition of health disparities in the guidelines as well. We are using the NCI definition. That includes racial and ethnic minorities. It includes rural residents; issues effecting women, children, the elderly, persons of lower socioeconomic status.

You also - in terms of research in the catchment area - can address environmental issues such as exposures; common behavioral problems that lead to higher cancer incidence or mortality; rare cancers in the community. There are a whole host of ways I think in which you can do this. And truthfully I think most of you are already doing this. You have clinical trials that bring in patients within your own community; the population studies which focus on the problems in your community. So for most of you I think this is not going to be a stretch. It's just a different way of presenting it.

The third question there is how does it fit in with the focus on global health and broader cancer research? And I guess I would just say all of these are perfectly fine. We're not saying that you are to do research in the catchment area exclusively. Global health is great. Cancer research that applies to broader populations is also great. I think our thought here was we fund 67 cancer centers in 32 states of the United States and that some research in the catchment area was probably appropriate, but it's not all we anticipate that you will be doing. You'll be doing the other things that you were doing before.

Will a scientific program be required to support cancer research relevant to the catchment area? I think the guidelines say 'as appropriate', so certainly you would expect to find it in clinical, translational, and population science programs. You might expect to find it in some kinds of basic science

programs as well but not all. So I think you have to think about what programs you are presenting and how this fits in with the goals of those particular programs.

And the last question was how is the cancer health disparity defined? And I think actually I've already answered that and it's in the guidelines on page 31.

So we had a question about addressing training and education and whether that had to be in the program write up. Actually no. Education and training are addressed in senior leadership and organization capabilities and on Data Table 2 - with all of your grants including training grants that will still be with each program. So we'll have that. But other than that - there's no write up for that in the program area.

Can centers apply to be exceptions to the caps? You can talk to us, but as I've mentioned the only exceptions to the caps really now are focused on those with unfunded extensions or very reduced awards.

So, finally let me just recap a few of the review questions we've received. I've already addressed the first one. Lunch is actually included in the five hour timeframe because we have an executive session during that time. Will there still be tours? The answer to that is yes, there will be a tour of the clinical trials office. There may still be tours of other shared resources if reviewers feel that it's important to see them. I think probably we'll keep in mind that there is an issue related to time, as we think about tours.

Will reviewers be trained in the new guidelines? Yes, reviewers will be instructed in the new guidelines, both site visitors and parent committee members. We've already had numerous discussions with the parent committee members about where we're going with the guidelines. That will continue. The

ad hoc site visitors will be instructed as well. Program staff and the scientific review officer will also be at the site visit and parent committee meeting to ensure that the new guidelines are followed.

What is the purpose of grouping shared resources and how do you suggest they be grouped? We are not predetermining for you how the shared resources are to be grouped. The purpose is really to align the shared resources in these groups with the science that the shared resources support in the research programs you're presenting. Keep in mind that both in the research programs and in the shared resources you'll be asked about value added. And so the purpose is really to make these coincide much better. The focus is on the importance of the shared resources to the science in the programs.

Shared resources are to be grouped into three categories to start out with. You may decide how to group those based on how they align with the programs that you're presenting. There's no predetermined way to do that. And then once you've grouped them into three you may add a fourth category that we're calling "Other" which will include any shared resources that don't cleanly fit into the other three categories that you've provided.

How is one merit descriptors determined for several shared resources? They will be voted on by group not individually. The review criteria will be based on the two review criteria that are in the CCSG guidelines now for shared resources using the full range of merit descriptors available. So you may get, for a group of shared resources, one merit descriptor such as excellent or you may get a range as you have before for an individual shared resource such as excellent to very good to outstanding.

So one other question which is not on the list about the shared resources, which is should we submit one budget for the group or separate budgets? You

submit separate budgets as before. The write ups are separate too, just as before. You'll just be asked at the time you submit information to us for pulling together the review team to group the shared resources as I described, and you will actually receive a review with one merit descriptor per group.

So I'm going to stop there and see what questions we have from the audience.

Shannon Silkensen: So, thank you Linda, very much for that. We've received a couple questions from people. One has to do with the sticky issues the catchment area again. Does the NCI have any expectation as to how much of a center's research will have to be devoted to its catchment area?

Linda Weiss: I don't think there is a prescribed formula...

Shannon Silkensen: Okay.

Linda Weiss: ...for that. I think it will probably vary to some extent by type of cancer center and also what the research programs are within the scientific foci of the center.

I guess in regard to this question I just might add one thing which is that in prior reviews if you've read your summary statement carefully, you have seen comments from reviewers about whether the center seems to be addressing cancer in its catchment area. So in a way this is not something that is brand new. It's more explicit than it has been before, but I think you have seen it consistently in reviews in the past.

Shannon Silkensen: Okay. Well let's move on from catchment area and talk a little bit about institutional protocol review.

So someone was curious about protocols that are reviewed by the institutional PRMS. Does the center still need to have this full protocol available during the site visit or will simply a list of protocols do?

Linda Weiss: I believe the procedure will be just as before. So we will still be doing the clinical trials office tour. If reviewers wish to see an individual protocol I would assume that it needs to be available.

Shannon Silkensen: Excellent. Since the clinical trials office is no longer being viewed as a shared resource, how should this information be presented during the site visit?

Linda Weiss: You're talking about the clinical trials office I presume...

Shannon Silkensen: Yes.

Linda Weiss: So if you look in the guidelines you will see what we are asking for, which is actually relatively brief for the clinic trials office. You're still going to be providing a version of tables that you have provided in the past. We described for you ways in which funds can be used to support activities in the same component. And we have asked you to discuss the role of the clinical protocol and data management office in relation to management and coordination of the cancer clinical trials of the center ensuring timely completion and initiation of trails and conducting effective quality control and training functions. And then you provide an overview and some tables are provided. So it's fairly brief but I think covers what we feel we think we need in relation to this component.

Shannon Silkensen: Great. Another review question that's come up. Do you know if there will still be a separate administrative review during the site visit?

Linda Weiss: That hasn't changed to the best of my knowledge. There will still be a separate administrative review. We still have administrative review criteria.

Shannon Silkensen: Great. Here's another question about review. It seems like the big issue for centers. This issue is scheduling time. Can we schedule time for reviewers to ask questions about application components that were not presented at the time of site visit?

Linda Weiss: So you do have some flexibility in terms of how you will present, for example, research programs at the site visit. You can spend more time on more complex programs if you choose to do that and less on more straightforward programs. You can actually - if you have a large number of programs - can choose to present some programs and not others. But every component, as we have discussed today, will have a ten-minute question and answer period associated with it regardless of whether there was a formal presentation at the site visit.

Shannon Silkensen: Great. So do you know how a shared resource serving multiple centers will be evaluated?

Lisa Weiss: I assume you're referring to the capability that we now have to purchase shared resources from other centers. So it probably is worthwhile to clarify that when you submit your own application. What we are primarily interested in in terms of budgeting and minimal usage information we're requesting is related to the use by members in your own center. So your budget would be predicated on that because, if in fact you are allowing others to purchase your own shared resource services, they're paying you and you wouldn't need to request money in your CCSG application.

If you are proposing the purchase of shared services from another center, you need to just follow the instructions in the guidelines related to what you present in the application for that. And that's in the development funds section.

I think there's probably a larger issue here which relates to the collaboration perk or angle. If it's a straightforward purchase or sale - if you will - of shared services then I think we only need what we ask for. But if in fact through this process, you are building collaborative science you may want to discuss that in a narrative of the program write up.

Shannon Silkensen: Okay. Let's change gears a little bit Linda, and talk about global health. Does global health apply only to lower and middle income countries or is it viewed more broadly, including Europe and other more developed parts of the world?

Linda Weiss: Well technically I think it's all parts of the world.

Shannon Silkensen: Okay.

Linda Weiss: Certainly the NCI is very interested in developing capability in underdeveloped countries and that's, for example, where the NCI Center for Global Health is directing its energies. Could you use developmental funds to participate in a study involving another developed country? I don't think we exclude that possibility in the guidelines. All of it has to get approval by the State Department, so all of it has to go through the Fogarty International Center and the first point of contact for that is your program director

Shannon Silkensen: Great. This is just sort of a basic question. Can applicants request travel money as part of the CPDM or the old clinical trials office budget?

Linda Weiss: Ah. I'm not sure that that's technically listed as an option. The purpose of the funds for the Clinical Protocol and Data Management office is really to support activities that centralize/coordinate clinical trial functions in the cancer center at a level one step removed from the clinical trial. I think I would have to have an example of what kind of travel might be requested. I don't foresee that we would pay for routine travel to a general meeting for a staff person.

Shannon Silkensen: Okay. There's another question about shared resources.

Linda Weiss: Um hum.

Shannon Silkensen: This comes from a basic cancer center. They say here that their resources stay within one scientific vein. Do they - must they group them in three shared resource bins or can they list them just as one set of shared resources during the review?

Linda Weiss: I don't see any reason why you couldn't list them as one group. If that answer changes we'll list it on the FAQ for you.

Shannon Silkensen: We have another shared resource question. I had a little bit of trouble reading it. So they ask for clarification. "We do not provide any more data regarding hours or FTEs devoted to these services."

Linda Weiss: I think what you're referring to is the capacity tables. So for example, if you had a stat core, you had to complete a table which showed what FTE you had devoted to it, how many hours the resource ran, and so forth. And the answer you probably would be delighted to know is no. You do not have to provide these capacity tables.

Shannon Silkensen: That's great. This is another question about shared resource grouping.

Does the NCI specify how the resources need to be grouped or is it up to the center?

Linda Weiss: It's up to the center. For example, maybe you want to group them essentially as basic, clinical, population, science, and other. Maybe you want to group those that are focused on high technology together. Really, completely, and totally up to you. And again, I want to emphasize: as you group the shared resources, think about how they're going to align with the science in the programs that you're presenting.

Shannon Silkensen: That's great. So speaking to science, let's switch from shared resources to the research program. As part of the application the new guidelines ask for a list of intra- and inter-programmatic activities and external collaboration. How extensive and what types of information do you want in this list? All external collaborations included or only certain types of these collaborations?

Linda Weiss: The reason we are asking for a list, as I think many of you know, is that this section of the narrative application was reduced from 30 pages to 12. So, we were trying to pull out as many components out of the narrative and put them into a list and make them part of the exclusions. As part of this list, I would say you should focus on the external collaborations and inter-programmatic activities that support the most science - the most significant programmatic science you want to highlight.

In some large centers, providing an exhaustive list of every collaboration that you have would maybe not be possible. So remember, that in the new version of the guidelines we're asking you to focus really on what you see has significantly advanced the science, made a difference for patients and their

families, or has been a fundamental discovery that changed the way we looked at cancer. We're not asking for exhaustive lists of everything, but certainly you should list there what you view as most important. What you want reviewers to see that will document, the importance and quality of the science that you're engaged in.

Shannon Silkensen: So the next question applies to a group of centers. So, for cancer centers whose application was submitted and site visit occurred in 2012, which new guidelines will become applicable and required for their first non-competing renewal and which will be grandfathered and governed by the old guidelines until the next competitive application.

Linda Weiss: So this is probably a question I should've addressed in the presentation. If you look at our website you will see in fact that we have new type 5 guidelines out for non-competing application. And these guidelines actually are premised primarily on the new version of the 2013 guidelines.

So let me clarify a little bit what our expectations might be in this regard because I've received a couple of questions. If you competed two years ago under the old guidelines and the clinical protocol and data management was a part of the shared resource component, are you expected to pull it out now and make it a separate component? The answer is no. You can leave it as it is until your next competing application.

But what I think you should pay attention to in the new guidelines. I understand that how much of this you can do will vary, depending on when you next compete, is . - you know, is really what we'll be looking for in the next review. So even if your Clinical Protocol and Data Management office – structurally remains a part of the shared resources during the entirety of the current project period, what we're going to be looking for at the time of the

next re-competing application is how you have addressed the new guidelines like making the protocol process more efficient. Those kinds of activities, I think, will still be looked at. So just because you're not competing for a few years doesn't mean you shouldn't familiarize yourself with these new guidelines.

We also expect that the data tables -, understanding that some of you may need a little bit more time than others - but the data tables will be coming in in the new format, you know, within the next year. So are you tied to the same structure? No. Should you pay attention to how the guidelines are changing and what you're going to need to demonstrate at the next review? Yes.

Also I guess I should just make the point that, you know, if you have questions about what you need to be doing in your progress report, your program directors are happy to talk with you further about that.

The other thing is you can also take advantage of some of the new pieces in the guidelines because whether or not you leave your clinical protocol and data management as part of shared resources or you decide to break it out, you can realign funds to cover some of the functions that are in the new guidelines. That's perfectly acceptable from our perspective.

Shannon Silkensen: Okay Linda, I think that really helps a whole lot.

Linda Weiss: Hmm.

Shannon Silkensen: Another question that we received on that issue I think we touched on a little bit ago. Someone just wanted to know when the non-competing guidelines will be released.

Linda Weiss: Yes.

Linda Weiss: I don't think we've actually sent out an announcement on it but they're up on the website - on the same page I believe as the - the competing guidelines.

Shannon Silkensen: Great. We have a question about the budget.

Linda Weiss: Um hum.

Shannon Silkensen: Somebody just had a clarification question. Please clarify the budget guidelines. If one has a current grant with \$2 million in direct costs, can one ask for another million dollars for a total of \$3 million or only 10% of the \$2 million or...

Linda Weiss: So this is - yes, I see where this is going. And this is why I gave the example. So you only can request \$1 million in total direct costs, if in fact that's more than what 10% would be if you added it on to your current award. So remember in the example I said if you have an award that \$700,000 it's clearly to your benefit to ask for \$1 million rather than 10% more. One gives you \$1 million, one gives you \$770,000. If you're above \$1 million already you cannot ask for a million in additional dollars. You can ask for 10% more than your current award.

Shannon Silkensen: So in this example the \$2 million direct cost award, it's a...

Linda Weiss: It would be \$2.2 million that you could ask.

Shannon Silkensen: Not the \$3 million?

Linda Weiss: Not the \$3 million.

Shannon Silkensen: Oh that's unfortunate. Well let's change the subject then to shared resources and groupings.

Linda Weiss: Okay.

Shannon Silkensen: There's lots of questions about grouping.

Linda Weiss: Hm.

Shannon Silkensen: So if the shared resource core group will have a simple score how does this score impact on the individual budgets within that group?

Linda Weiss: Maybe single score?

Shannon Silkensen: Oh excuse me...

Linda Weiss: Single score...

Shannon Silkensen: ...single score.

Linda Weiss: ...not simple score. Single score. So you - as I mentioned you're going to send in a budget for each. It is possible that the review team will allot a lump sum across each grouping. You should have the opportunity to work with the Office of Grants Administration in the budgeting process once the award has been finalized to distribute those funds as you see fit. You can equalize them, make them all equal if you want to do that, or distribute more to one and less to others. I think that's a negotiation that takes place after the review, between you and Grants Administration.

Shannon Silkensen: Great. So again, talking about shared resources, Linda.

Linda Weiss: Um hum.

Shannon Silkensen: Can you elaborate more on shared resources? Do you mean sharing cores or resources between institutions? And if so, only with other cancer centers or are they with other NCI-supported centers all right as well?

Linda Weiss: At this point it's just with other NCI-designated cancer centers because well - there's some logistic issues that we just have to deal with here. I think in concept we've always been supportive of trying to access high quality shared resources where you can. But this is sort of the introduction to sharing resources, and for right now it's restricted to other NCI-designated cancer centers.

Shannon Silkensen: All right. Well let's leave shared resources...

Linda Weiss: Okay.

Shannon Silkensen: ...for a little bit and talk about senior leadership. So, can you talk a little bit about what is meant under the new senior leadership expectation of “establishing a process for integrating training and education is the program out of research?” Can you give us an example of what are - what's expected here?

Linda Weiss: Sure. If you actually look on page 21 of the guidelines - we've listed some examples and there may be other examples. These aren't meant to be exclusionary. What we want here is just to know that the senior leadership

group as a whole has some oversight, of the training process; that they are looking, on a center-wide basis, and to how training might be integrated.

And we're not dictating how that occurs. There are some centers that have associate directors for training and education. And we actually provide some support for these ADs. Sometimes there's a center-wide committee that focuses on helping all of the training efforts coordinate, integrate. They monitor education and training efforts. You can also include in this regularly scheduled meetings and retreats. There's are a number of other things listed there.

And we've also noted that how this process is set up is probably going to vary by type of center. For example, you may not see the same thing exactly in a basic center that you would see in a comprehensive cancer center with many kinds of programs crossing the entire spectrum of the cancer continuum.

Shannon Silkensen: All right.

Linda Weiss: And I guess I just want to emphasize the process, establishing a process. Right now we are not looking for lists of mentees or lists of your education and training efforts. In this section, we want you to discuss how the senior leadership is organizing, overseeing, kind of looking toward integrating these efforts so that it really enhances the scientific roles of the cancer center.

Shannon Silkensen: So another question on knowledge and resources when it has to do with global health.

Linda Weiss: Um hum.

Shannon Silkensen: And so the question is sort of akin to the conversation we had earlier.

Linda Weiss: Um hum.

Shannon Silkensen: If global health includes any part of the world, is the requirement that Cancer Center investigators actually conduct research there or can they collaborate with investigators in other countries by providing for it intellectually but not performing the study itself?

Linda Weiss: I think that there are various levels of involvement that we see in these kinds of projects, so I'm not sure that it's necessarily true that you have to have a project yourself going on there. Obviously if you're using development funds though or you're using protocol-specific research support funds but - that have to meet the criteria for those components. And so you can do all kinds of things in terms of global health. But how you use the funds in the Cancer Center support grant is really tied to the criteria.

So I think we specifically state for example in EPCRS as you can use it for a global health project but it has to meet all the other criteria for protocol specific or early-phase clinical research support. So just be careful there.

Shannon Silkensen: And another question that we might get to in the next Webinar dealing a little bit about data tables. It has to do with the inclusion of women and minorities in clinical research.

Linda Weiss: Um hum.

Shannon Silkensen: So someone was asking is it possible that centers could delay the reporting of non-interventional accrual in the non-competing submission to follow up application in order to allow time to adjust for processing to aggregate this data into a centralized database?

Linda Weiss: Actually you're not required to submit...

Shannon Silkensen: Submit...

Linda Weiss: ...accrual data in non-competing applications, only in competing applications. So in this instance I would say it's a fairly straightforward yes.

Shannon Silkensen: How should centers present training that's conducted within the CTSA be included in the cancer center?

Linda Weiss: Well obviously it depends a lot on how you yourself have structured the training programs. In some centers I know they had worked very collaboratively with their CTSA's to integrate oncology kinds of training grants and programs with other kinds of training grants and programs. In others they have joint committees that decide on how funds specifically through the CTSA might be dispensed and Cancer Center investigators have the opportunity to obtain funds. It's really very institution dependent I think certainly where it's a positive for the cancer center to present that information and you benefit strongly from CTSA in your institution in terms of training or any other area: shared resources, developmental funds. I think it's very appropriate that you discuss that in the application, maybe in the director's overview or other areas that are pertinent.

If you're integrating to introduce efficiencies - for example in shared resources, if you've worked with a CTSA to set up new kinds of shared resources that service investigators on an institutional basis that might not have been available had you either of you been working on your end. I think those are important things to talk about. So I would say, generally speaking,

highlighting the positive both in terms of integration and how center investigators have benefited it's probably worthwhile to do.

Shannon Silkensen: Well Linda, I want to thank you very much for being here. To close...

Linda Weiss: Um hum.

Shannon Silkensen: ...I think we have one last question which is sort of...

Linda Weiss: Um hum.

Shannon Silkensen: ...a forward looking question.

Linda Weiss: Okay.

Shannon Silkensen: And it has to do with what are the plans to amend the new guidelines? To address the conversion from the PHS 398 to the SF424 and an electronic submission?

Linda Weiss: Well I wish we knew. As you may know, the SF424 is, mandated at a government-wide level. And we've - a couple of us -, have sat in on a few meetings around the SF424 as it relates to complex applications. As I think we've indicated via a couple of emails that we've sent to you, the current plan is to implement the SF424 for the P30 with January of 2014 applications.

But right now we don't know what that's really going to look like exactly. It may mean changes in sequence of the components of the application, in format and - I think we probably anticipate that we may be looking at some amendments in the guidelines and the FOA to accommodate that. But right

now we don't know what those are or when we'll have notice of what those are going to be, so.

Shannon Silkensen: Well, great. Well I'd like to thank you for participating in our Webinar series and thank all of our participants online. And keep your questions coming. Thank you.

Linda Weiss: Yes. And again I just want to say that if you want to send us questions we certainly will try to take a look at those and incorporate them into our FAQs. And I know some of you may have more complex issues and we can certainly deal with those offline as well. So, thank you.

Shannon Silkensen: Thank you.

Sandy: Thank you. That does conclude today's conference call. Thank you for participating and you may disconnect at this time.

END