Pre-Application Technical Assistance Workshop

Social and Behavioral Interventions to Increase Solid Organ Donation HRSA-12-034

Moderator: Rita Maldonado **September 20, 2011** 2:00 pm ET

Coordinator:

Excuse me, this is the Operator. At this time the call is being recorded. If anyone objects they may disconnect. I'd like to turn the conference over to your speakers for today, thank you.

Rita Maldonado: Thank you. Okay, thank you. We'll get started here. It sounded like we had a few more people call in so I would just like to thank you for joining us. And like the operator said, this call is being recorded so we will be able to provide it to people who are not able to join us today.

> I would ask that if you have any questions that are specific to your project that you please hold those to a separate call or an email and you're welcome to contact us at any time with your questions. So - but if you have a question that you think pertains to a larger audience I welcome you to ask that on the call today.

I encourage you to jump in if you have a question. It can get a little dry if I'm just talking so please jump in. Otherwise, I ask you to keep your phone on mute so we don't have any background noise.

Sounds like we have quite a few people joining us. We'll have introductions in a moment. My name is Rita Maldonado. I am the Project Officer for this (unintelligible) and on the phone we also have Bruce Holmes. Bruce, do you want to introduce yourself?

Bruce Holmes:

Afternoon everyone, I'm Bruce Holmes, the Grants Management Specialist standing in also for Mr. Brad Barney who is the Lead Grant Specialist on the Social and Behavior Program and on behalf of Mr. Rick Goodman, our Division Director, and Mr. John Gallicchio, our Branch Chief, we welcome you.

Rita Maldonado: Thank you, Bruce. So I would like to open up for everybody to give an introduction if you could give your name and organization that would be great. And we'll just have to jump in since we don't have a table to go around.

(Bertha):

(Bertha) (unintelligible), Going Forth Community Development Corporation, Decatur, Georgia.

Woman:

Hi, (unintelligible) University Hospital.

Rita Maldonado: Anyone else who'd like to introduce themselves?

Woman:

(Unintelligible), Presbyterian Hospital.

Rita Maldonado: All right, well, I know I heard a few more beeps but that's okay. If you'd rather remain silent that's fine. We'll get started.

> So today we're going over the Social and Behavioral Interventions to increase solid organ donation grants program and this is HRSA-12-034. I'd ask that

you have a copy of the funding opportunity announcement in front of you. I'll refer to it as the FOA from here on out. And we will be going through this page by page and I'll be pointing out really important items that you want to pay special attention to.

On the cover I want to make sure that you have the correct year. So we are looking at Fiscal Year 2012. And it should have - right below the Fiscal Year 2012 a line that's underlined that says modified on 8/31/11. There was an error that we recognized that on the original posted FOA. It was corrected and reposted so if you don't have that version I encourage you to go back to Grants.gov and download that version.

You can also on Grants.gov signup for any future announcements so if - pertaining to this grant program. So if you - if there is another change that's made down the line you'll get an email alerting you to that change. So please do that as well.

The application due date is November 30, 2011. Later on you'll see that that is due at 8:00 pm Eastern Time. So please make note of the date and time.

And my contact information is right there at the bottom. Like I said before, you're welcome to email me or call me at any time with your questions.

Great, so we'll move on to Page 1. And first and foremost, I want to encourage you to look at the goal of this program. There are two goals and you're welcome to choose between the two in your application. The first is to reduce the supply and demand gap between those who need organs and the numbers that are donated. And this is through identifying successful strategies that can serve as model interventions to increasing deceased organ donations.

Number two is increasing the knowledge of options available through living donations among patients who may need transplants and/or individuals considering serving as a living donor. So please be aware of the distinction between the two.

And if you are looking at Goal 1, and that's increasing deceased organ donations, there are two ways that this can be done. And they're outlined below. One is through individual commitment to becoming a deceased organ donor and documentation of that commitment, that's typically through a state donor registry.

Two would be consent of family for donation when a person has died so at the bedside. Three, again, if you're working on Goal 2, there is just one objective there and that is, again, the knowledge of the processes, risks, advantages, and disadvantages of deceased and living donation among patients who may need an organ and/or individuals considering as serving as living donor.

So you need to indicate in your application which of these objectives you are looking at increasing.

At the very bottom of that page, actually in the footnote I encourage you to read that closely. It defines organ for the purpose of this application. And this is important because while you can increase tissue and eye donations the focus of this program isn't to increase the solid organ donations. So be sure to be aware of that when you're working on your application.

Now jumping up to the last paragraph on that page and into the next page, there's further discussion about living donation. The government is not in a position of promoting living donations because of the risks that can be posed on to the living donor and the lack of evidence around exactly the outcomes.

And so what we have listed in this grant program is you can increase the knowledge, again, about living donations but you cannot promote living donations. So if you are working on a project that seeks to work around living donation I encourage you to read this very carefully and to call me if you have any questions and you would like to discuss it further.

On Page 2, just a little bit more clarification, something that's actually new to the FOA this year. If you are working, again, in a living donor project you will not be eligible if you are measuring an increase in the number of living donors or increase in the individual's readiness or willingness to pursue living donation. So just be sure to review that language and - so that you aren't proposing to do any of those things that will make it ineligible.

Okay, Further on down you'll see that for all projects that are - come in under this grant program, the evaluation component is really key. It can really make or break a project in a lot of ways. And the reason is that the purpose of this grant program is to create intervention that can be proven to be successful and then replicated and/or even made into best practice by others - people throughout the country.

So the evaluation component is very important in this project. Because of that there is a cap on the development of the intervention so the last sentence in that second paragraph, you'll see in highlighted that no more than 20% of total direct costs and staff time may be used for development of the intervention.

So you'll be asked later on in your budget certification to indicate which items are part of the development costs so that you can show clearly that the - that you're falling within those guidelines.

There are three types of projects that you may do. One is a pilot project, that would be something completely new to the fields and something that's never been tested before. An extension project is taking a previous pilot project and making it on a larger scale, maybe adjusting it or adding something new.

And replication project is taking something that's been previously shown to be successful, replicating it as it implies, and in either a different setting or with a different population. If you are doing a replication project you must include one minority population in your study.

Also, if you're doing an extension or a replication project you'll want to clearly describe the original study and provide some rationale for either extending or replicating that study in your area.

You can use multiple strategies as well. If you do that, however, you need to be very clear on how you will be distinguishing the independent effects as well as the interactive effects of those multiple strategies.

So as you can see, having a strong evaluator who has experience in social and behavioral interventions is really key when submitting an application of this type.

All right, on to Page 3. We'll talk about funding restrictions a little bit later on but they - there are some listed here as well. I mentioned already the restriction on promoting living donations. Also, you cannot do biomedical or clinical research or do research that has to do with donor management, organ recovery, organ preservation, or there's some other items listed there in that third paragraph down. Be sure to read that clearly.

We encourage collaboration. A consortium would be two organizations, one with the expertise in organ donation outreach and the other would be an organization with expertise in social and behavioral sciences. However, in previous years we did have a funding priority associated with a consortium.

This is no longer the case so you will not receive any extra points above whatever the reviewers score you at but if you do have both of these organizations represented it could work in your favor if it goes to show that you have a broader base on to which to carry out a project like this. However, there may be some organizations that have expertise in both and they would not be penalized there.

Page 4, the background. I will let you read most of this on your own. I do want to point out though that this grant program has been around since 1999 and there has been 92 research projects totaling \$67 million funded through this grant program.

If you go to OrganDonor.gov there's a Grants tab and you can read summaries of all of those grant projects that were funded in the past. I encourage you to do that. You may get some ideas for either projects to replicate or just projects that might give some insight into background for your own to build on.

Also, on OrganDonor.gov is a bibliography of published literature that has come out of our grant program. So I encourage you to read that and include references from those in your applications if appropriate.

Other information on Page 5, you can read those resources as well. Bottom of Page 5 you'll see the summary of funding. We have approximately \$1.25 million available to fund four to five projects. And these would be carried out - this is up to three-year projects and it's carried out from 2012 to 2014. The

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average award ranges from \$250,000 to \$350,000 per year. So range is not a

minimum or a cap and so you are welcome to come in below or above that

amount.

Regardless of the amount that you request it has to be well justified. And then

the number of projects that are ultimately funded depends on the amount that

people requested.

On Page 6 you'll see eligibility requirements and this has to do with public

and nonprofit status. Please review that and make sure your organization falls

within those guidelines. And your application must be submitted through

Grants.gov, no paper applications will be accepted.

If you have some sort of extenuating circumstances you may request a waiver,

however, this is rarely awarded and in this day and age it's best to just find a

way to work through Grants.gov to submit your application. I encourage you

to submit at least three days early though because there are times when the

system gets backlogged or some other thing happens.

And if it's because the system's backlogged you will not get a waiver. They

say, well, no, you could have submitted it earlier. If in the case of a natural

disaster there is contact information for a request for a waiver and those are

sometimes given but I just encourage you to submit three days early. If you

find that you want to resubmit we'll take the last application that was

submitted.

On Page 7 you are limited to 80 pages and/or the 10 megabytes. It's really the

smaller of the two. So if it's - just stick with the 80 pages printed out before

you apply and count the pages, make sure that you fall within those

guidelines.

Are there any questions to this point? Great. I'm going to pass this on to Bruce.

Bruce Holmes:

Okay, good afternoon everyone. Once again, in case you are joining us after the beginning of the conference, I am Bruce Holmes the Grants Management Specialist and I work with Mr. Brad Barney who is the Lead Grants Management Specialist on the Social and Behavior Interventions to increase solid organ donations.

This afternoon regarding the budget matter I am going to cover a few of the grant's characteristics and requirements for submission and funding, meeting the funding opportunity announcement requirements. Some of them will be reiterated for - because they are very important items as Rita just mentioned here. I will be going over some of the forms matter, the budget narrative matter, again as I stated, some of the submission items. And then I'll have a quick Q&A item.

At this time I do believe that we do have a few folks that are new to the federal grants process. I'd like to welcome the fiscal staff that's out there. I think I heard one person that's a business fiscal agent out there or a grant manager out there, welcome aboard.

Okay, reiterating on some of the housekeeping rules regarding submission, make sure that you are submitting applications before 8:00 pm, November 30, 2011. Anything thereafter, unless it's an act of God meaning nature or something prohibited you from submitting as Rita stated, it's very rare now that waivers are granted. Be sure to comply with the request for waivers as mentioned on Page 6.

The budget period and project period, as you see there it states that the funding will be for the fiscal years 2012 through 2014. As you know, the government runs on a calendar. Their fiscal calendar runs from October 1 through September 30 of each year.

So your budget periods for this grants which are the 12-month funding increments of the project period, the project period is the tenure of the entire award - award period for the grant, which is the beginning date of the award to the ending of the project period.

The awards, we are anticipating to have them out - should all go well for bidding, any unnatural disasters or anything else, hopefully we'll have these awards out the door within 60 to 90 days and no later than the first week of the start date.

Again, the start date is September 1, 2012. Rita's reiterated the amount of money that's available there on Page 5. So if you need to refresh your memory on that one please go back to Page 5, read those.

On the eligibility requirements, Rita did mention that this is for public and nonprofit entities. However, be sure to read that during that first paragraph at the top of Page 6 under III Eligibility Information and Eligibility Applicants. It does mention the specific parties such as for-profits and nonprofits, state and government local grantees, Indian tribe governments, etc., educational institutions.

I did notice that - and please be informed that each one of the entities that your organization fits in has its own unique cost principles and those are listed within the funding opportunity announcement and the resources in the appendices. If you do have questions and can't find that information please

give Rita a call and if she cannot answer the question field those to Mr. Barney or myself and Rita will put you in contact with us.

Again, reiterating because of the importance of it, no later than three days prior to - or you should submit your application as early as possible. With that submission process every applicant - every application is required to have a DUNS number at the time of submission to try to - or a DUNS number will not happen.

You will need to do that now and between now and the - excuse me, the submission time and have your DUNS number set. Also have the organization a complete registration made out and the central contractor registry, that information guidelines is - are mentioned on Pages 6 and 7. Again, if you have questions please send us a call and we'll be able to assist you.

Page 5, it is critical that we reiterate that to you, 10 megabytes or 80 pages max. And as was mentioned there, you should print out the document to make sure that you have the correct count - page count.

If you're concerned about a Table of Content a Table of Content is not required but if you elect to use a Table of Content, noting on Page - that's entitled, Table of Content, i under Section IV Application and Submission Process beginning at 2 where it says content and form of application submission, if you follow i through II right through attachments, that's the order that you want to run your Table of Contents in.

Now as promised we'll move over to the form part. As a part of that, because page count is important please be advised that the forms kit or any form that's used within the application, forms kit, which is the 424 R&R (unintelligible), research and related grants form kit, will not be counted in the page count. On

Pages 9, 10, 11, and 12 and the far right column entitle HRSA/Program Guidelines, it iterates which pages will be counted and which pages will not.

At this time I would like to kind of go over the form pages briefly with you kind of - it's summarizing the outline of the budget forms and the application forms on Pages 9 through 11.

Each budget section or group of budget pages runs through - it's - on my printout it's three pages but for you you'll be able to fill out as far as the forms, it runs from Items A through K. As I prefaced it, understand this, one item concerning the characteristics of the grant.

When you're applying for a grant you may have multiple partners on the grant, which is usually called a consortia in the donor organ transplantation world or - but only one person, one applicant, not person, one applicant or organization will be the fiduciary, fiscal responsible agent for the grant.

That person - that grantee or that applicant that's the fiduciary responsible agent, that indirect cost if indirect cost is requested, the indirect cost agreement that's registered with the Division of Cost Allocation will be the indirect cost rate used.

I'd like to reiterate, if you have a contract or a consortia member, meaning multiple partners on there, you will not use the subcontractor consortia members indirect cost rate. You'll use the applicant's approved indirect cost rate.

Within the guidance you'll find a section on there on guidelines on indirect cost rates. So now picking back up on the forms section and now we'll say that for each applicant as well as consortia member or contract or sub-

awardee, each person must complete Sections A through K. Each applicant and consortia member or sub-contractual member will have to complete a set of forms, which is comprised of letters A through K, that's a set of budget forms.

Okay, beginning at Section A - Section A starts up with Senior Key Personnel. You will be required there - the forms are self-explanatory but I want to reiterate that you are required to submit the base salary as well as the requested salary. Within there you'll notice there are three columns inbetween base salary and requested salary; their calendar month, academic month, and summer months.

Those are primarily for educational institutions. If you have questions regarding those in breaking out those months or the base salary and requested salary please submit a question or an inquiry to Ms. Maldonado and she'll field those out to me and we'll take care of you and answer your question.

If you've run out of Senior Key Personnel lines there is an attachment built in within the application kit where you can add in additional Senior Key Personnel. In Section B, it's the other personnel. Those are your post-grads, post-doctorial associates, grad students, undergrad students, secretarial, clerical, and other support staff. Any one that does not fit categorically under principle staff go under other staff.

Also recognize too that even though the owner of the grant is the applicant organization the human contact or the program director/principle investigator is the principle contact and responsible party along with the applicant organization for the grant.

Any time you have a grant please be reminded that on the face page when you're completing the face page, the names that are on the face page are the names that will be listed primarily on the distribution of this grant which will usually be to the program director/principle investigator and then the point of contact is listed there.

And then also you have - the point of contact should probably be, it's recommended but not required, but I would strongly recommend that that be the business/fiscal agent.

Pay particular attention to the - filling out the face page of the application, you want to make sure that you have the name of the PD in there, notice where it says POC which is the point of contact and then also you have a business address listing requirement there, two different things. The organizational address and the fiscal addresses are very important, make sure you enter those.

If you have - and when you have your - what's called an EIN, an Employee Identification Number, make sure that if you have one that's already registered and you have other federal grants, be sure to list the extensions that are already on your current EIN; very, very important for funding purposes.

Section C, Equipment Distribution. Categorically equipment is listed as \$5,000 per item. However, you're not restricted to that if your organization considers an item to be equipment and it's under \$5,000 two things; one, we will accept that; two, be reminded that if it's considered as equipment even though it's less than \$5,000 categorically - categorizes equipment and it's les than \$5,000 by your organization's policies then it cannot be counted toward the indirect cost. If you run out of space there, listing your equipment, you can upload additional pages in there.

On travel, within the travel section, applicants are reminded to complete - and that is with each budget category. Please refer to the definitions of the budget categories which began on Page 15 or actually instructions start on Page 13 and run through Page - Pages 16. So that's Pages 13 through 16 which gives you descriptions of this information.

And I say that now because one of the mistakes that grantees make are - is usually when we ask for a budget narrative they'll transfer - like for example on the personnel cost, those line item information that's there but they don't give you anything of substance of what it's about. I'll go into that in a little bit more detail.

But on Item D, Travel, picking up on this, I'll try to stay focused on this form for you, be sure to list in who's going to travel, where they're going, why - who, what, when, where, why, also to include your travel.

If you need to do final presentations at the end of the grant, please do not forget to include your final - any travel that's involved in your final presentation because you more than likely will not receive additional funds for travel if you forgot to do that during - to include that in your budget. And I believe that's in the last year of your grant.

Item E is very important because this is not a trainee grant but we do have under this program - under the donor organ transplantation social behavior program, we have participants who are involved in the study. So if you have participant costs list those in Item E.

Also there is a common item called Incentives. Incentives for the grant are items or monies that are paid to person participating on a survey or any other instrument for research purposes on the grant or to obtain data for the grant.

I'd like to reiterate on that, any work that's done on the grant individuals are expected to be paid for their work.

I say that to reiterate that you cannot recompensate persons for grant work by taking them out to lunch or giving them a donor gift card. If they're working on the grant they should be paid cash on the grant.

Food costs, on the food costs, please listen very carefully and also - and understand that if you have a business-related meeting that pertains to the approved objectives and goal of the grant, usually food would be allowed for a business-related meeting that specifically rates to - it discusses or - to discuss approved goals and objectives of the grant.

If you have a meeting within your grant and you are contracting or using a facility such as a hotel or an any other forum, venue, and the food costs are included as a package deal then food may be included.

If you're having a meeting and you're in your office and you want to cater that out, not allowed. Additional catering is not allowed. Packaged cost as part of a packaged deal, food is allowed. If you have questions please send any questions, any cost questions to Rita and we will be glad to entertain those.

On Item F, Other Direct Costs, materials and supplies, that information categorically is lifted. You'll have publication costs, consultant costs. Consultant and contractual costs are two different costs, that information is provided in your guidance and because the social and behavior applicants do such a great job on this I am depending upon you to read the categories on there and what - how to complete the line item numbers and the narratives. But I'll go over some of those narrative items shortly.

ADP, if you see it's under Item F4 under Other direct Costs, that's Automated Data Processing costs so computer costs. Item 5, F5, and if you'll recall earlier as we said under the sub-awardees - if you have a sub-awardee or consortium or consortia-met group, contractual costs, each one of those entities will have to submit a section of budget forms A through K, and also add as a caveat on to this, a budget narrative to support this.

Unlike the past we cannot allow this to be bypassed and if you're more than likely - if you're not providing complete information you could run the risk of not being funded because of an incomplete application. This is a mandated requirement that the sub-contractees at the first echelon submit budget forms and a budget narrative, which is mandated by the Executive Offices of the White House. It's a mandated requirement.

On Section 6, F6, if you have any facility, rental, user costs or fees, that's where you'll include those costs. Pay careful attention, those costs are not included in your indirect cost rate. Grantees are allowed to under Item H 1 through 4, if you have multiple indirect cost rates, those are allowable. Please notice that Items A through G comprise the direct costs, total direct costs, which is what we heard earlier.

You're going to be concerned about 20% of those total direct costs and staff time, which you have the limitation regarding your development cost as iterated on Pages 14, under iv Paragraph 2 that regards that. So that's your - where you'll find your total direct cost figure.

And of course, on Item I, Total Direct and Indirect Cost, that's - total direct and indirect cost includes the total funds for the cost for the budget period. Slightly above that under Item H regarding indirect cost, the cognizant federal

agency, that is the agency from who - which approved your indirect cost rates agreement.

Okay, that - concerning cumulative budget page, after each set of budget forms, that's Items A through K - actually it's A through J but I only - A through J, the system generates a cumulative budget page after each budget period but does not provide a collective budget summary. Don't worry about a consolidated budget for all of them - for one of them, the system generates one page after each budget period.

And you will need to complete - it's very, very important that you complete a budget section, that's forms A through J, for each budget period of the tenure of the project. We iterated that this is a three to four year project period - budget period, that means that if you have four years requesting four years of funding you need a four year - four budget sets of forms completed and four budget narratives.

Correction, on the budget narrative or the budget justification, and we'll be moving over to that which is found at the beginning of Page 14, the budget justification can be truncated. What we're looking for in the out-years after that is after Year 1, any changes to the out-years, that's Years 2, 3, and 4 that are being made to there, that's where you can include the out-year budgets.

We don't expect you to do four separate budgets totally but what I'm saying is for space concern and page count purposes, you can truncate the budget in that regard. However, you will still need to include enough substantive matter for the objective review committee and HRSA staff to interpret or support the budget which you are requesting.

Because this is a lot of information and we do have first time applicants here we like to ask if there are any questions regarding budget matter and

submission process to this point.

Hope I didn't put you to sleep. Okay, we'll move forward. All right, on Page 14, the Budget Justification. The Budget Justification as we stated, you have to fill out more than - fill out one budget period - one budget justification and provide enough budget data or items that change in Years 2, 3, and 4.

For example, what I'm saying when I say submit a truncated budget, you'll

have under your personnel - and if you're looking over on Page 15 it's says

personnel cost.

Personnel costs should be explained by listing each staff member who will be supported from funds named if possible, the name of the individual, position/title, percentage of fulltime equivalency, and annual salary. What we would like to provide in there specifically is to know that - describe the administrative and managerial capabilities of the individual, state their relationship to the project.

The key point in a budget justification is that the goals - the budget that's requested logically relates to the narrative and the project objectives; logically relates to the narrative and project directive.

And for the personnel costs there, for example, you're going to say, okay, XYZ Principle Investigator will have overall responsibility for all aspects of the project. He or she will oversee all content, development, implementation, and evaluation and reporting activities.

He or she will devote 20% FTE of fulltime efforts to this task, that's enough information for the review committee to look after. And you should provide them the minimal of that but not restricted to this, what I've requested here but enough that we can justify that position.

Also be advised that all personnel that are being funded by the grant cannot exceed 100% total effort on all federal grant work throughout the federal government combined grant work - cannot exceed 100% of effort. If you have five grants and you have one person working on five grants, five federal grants, that percent of effort cannot exceed a total of 100% effort; very, very important.

Fringe benefits, that information is explanatory on 15, Item 15. You are strongly encouraged, especially - I know in organizations, educational institutions, if you have a sponsored programs office and if there are new staff onboard there, make sure that - use the program director and the fiscal agent and the fiscal parties or the program director principle investigator touches base with your business office or whether it be a sponsored program, mediary office, or the main campus fiscal office before submitting your application.

We've had situations where grantees submitted applications, business office had no idea, they lost the grant.

Another point why it's very important to be as detailed but yet truncated as possible in the budget is that we are not requiring you in the out-years as has been in the past to submit a full application. You will only be submitting a program progress report. So we're relying upon the information that's provided for you in this grant to justify the funding for the entire project period or each 12-month increment of the project.

We talked about travel. You want to make sure that you include in the travel costs your TA workshop costs. If you're including conference costs in there - try to not just generalize and say, just for the sake of adding money in there or we're going to send folks to four annual conferences at the Social and Behavior Society.

Justify why you're doing that. If this is directly related to the grant then you should send those to the conferences. Only relate the budget matter to goals and objectives within the project.

We talked about equipment. We talked about supplies. As listed within the supplies we're looking to make sure that it's reasonable and necessary and allowable. And of course, you always look at your allowable costs within the cost principles.

We talked about the contractual costs. Each contractor must be registered at the central contractor registration.

Other costs; other costs are any costs that cannot be logically linked or identified or associated with any costs that are listed on the budget form. We talked about indirect cost rates. There isn't a cap on the indirect cost rates here but if you do not have an indirect cost rate at the time - approved indirect cost rate at the time of submission you will not be allowed to include indirect costs.

You must already have an approved indirect cost rate. This is not the policy of HRSA. The Division of Cost Allocation is a separate federal agency along with other indirect cost rate entities or - I think that there's one in - the National Institute of Health that manages for-profit organizations where

you're paying your indirect cost rates there. So that information is found on Page 16.

And let's see, what else did I promise you? Okay, we talked about the narrative. We talked about the submission process. We've talked about specific - about including your budgets a final presentation cost. And I think that's just about all that I have for you here.

Just remember the importance of the forms and submitting a complete, succinct, and comprehensible budget to the best of your ability. And I'll turn it back over to Rita if we do not have any questions.

(Halley):

Hi, this is (Halley). We just have one quick question, I'm sorry if I misunderstood. In terms of the consortia, perhaps if we team up with an organ donation group etc. that's not for profit, I understand they have to have their own CCR. Do they need their own DUNS number? I'm not familiar with that?

Bruce Holmes:

In order to work with the government and get paid, the way that they get paid - for this grant purposes, the person that - the DUNS number we're concerned with is the applicant.

(Halley):

Okay.

Bruce Holmes:

Consortium and contractual approaches, if they're registered with the CCR I believe are required to have a DUNS number as well but you should ask that question - direct that question to the - (Brad) in DUNS (unintelligible) Agency and to the Central Contracting Registry.

You know what I'll try to find the answer out before we end this call.

(Halley): Okay, thank you.

Bruce Holmes:

Reiterating on that, that was a good question and making sure that everybody understands, the question regarding the DUNS number and CCR registration. For the applicant organization, for example, if Buford Educational University is submitting a grant and Indiana State and Kentucky State are working with them on the grant, Buford Education is submitting the application.

Buford Education or the working relationship will be with Buford and not with Indiana and Kentucky. Indiana and Kentucky are considered as consortium members or contractual members or however they may be categorically identified. And they do not have communication with the federal office. Their business relationship is with the applicant or the grantee.

And each entity should have a DUNS number or CCR. And I'll verify that for - concerning the consortia/contractees after I complete my segment.

Any more questions please?

Woman:

About the budget though? If I could - I'm wondering, I was listening to the other call about public education efforts to increase solid organ donation as well as this one. And is the main difference between the two is that this one is more research oriented and the other one is not?

Rita Maldonado: Yes, that's correct. This is Rita. The public education effort is really about carrying out of projects that has already shown to be successful. So the funds are really there to roll out a project. It does have evaluation component but it's much smaller. This is really about doing research to see if something new - if a new intervention works for increasing donation.

Woman: And I thought that was clear to me and then you started talking about that -

how we can do a replication project for the social and behavioral intervention.

Rita Maldonado: Yes, and that's where they sort of start to get similar. But the replication here

is really about trying to do something in the new area or new population and

so it is somewhat similar but...

Woman: Okay, thank you.

Rita Maldonado: And if you want to talk to me offline about which you - which might be better

to apply to I'm happy to do that.

Woman: Okay, thank you very much.

Rita Maldonado: No problem.

Bruce Holmes: Also, on that note that was a very good question regarding - budget wise,

understand that if you have, like, in this case we have the public education grant program and the social and behavior donor program, always remember that each grant is considered a separate grant and those funds shouldn't be comingled if you should have both grants awarded to you, one public ed and one

donor organ.

They are separate grants and they don't kind of cross over although

programmatically they are related. Just wanted to put that out there.

Rita Maldonado: Well, thank you Bruce. There's one thing that I just want to really emphasize

and Bruce already mentioned it but - about the budget justification and that is

that the objective review committee can cut back on your budget.

And the reason they would do that would be because something isn't justified or it doesn't relate back to your program or it's seen as something - an excessive cost for something. So whatever you do you have to justify every single item well.

And one of the things that Bruce was saying was that you can truncate it by include - saying - giving a full justification for Year 1 and then Year and 2 and 3 saying the same is true. But be careful because - for example, if you're talking about a personnel category and saying in Year 1 the person will be developing the program, implementing the program, and on and on.

Then - and then you say in Years 2 and 3, the same as Year 1, but in actuality your timeline doesn't include anything about development in Years 2 and 3. They may say, well, you - they're not doing development in Years 2 and 3 and so we're going to reduce it by so much in Years 2 and 3.

And it may be the case that you didn't mean for that to happen. So just be sure that you cover your bases in your budget justification. It really is a crucial document.

The other thing that I wanted to reemphasize about the budget is that we do have technical assistance workshops that you're required to attend. There are two in the first year and one in each subsequent year. And so you need to budget for two individuals to attend from your full project.

So it may be one person from the applicant organization and one person from a consortium organization or any combination. But no more than two can be paid for by the grant. If your organization wants to pay for additional people to go that's perfectly fine but they cannot be funded by the grant. This is another area that sometimes gets cut.

So be sure to include that, the cost should be based on travel to Washington, D.C. The first meeting will be in Washington, D.C. The subsequent meetings probably will not but the - if you budget based on the D.C. cost then you should be able to cover the cost wherever the meeting is held.

Bruce Holmes:

Also, the answer to the question regarding the registration of contractual consortium, etc., that is found on Page 15 on the last sentence under the paragraph in the Budget Justification entitled Contractuals.

It says, remind the receipts must notify potential sub-recipients, contractors, consortiums, sub-awardees, etc. that entities receiving sub-awards must be registered in the central contractor registration and provide the recipient with their DUNS number.

So the contractees have to be registered in the CCR but it sounds like the applicant or the awardee - use their DUNS number to provide the recipient with the DUNS number. I need to get clarification on that too. Okay, but that's where that's there and I'll have a final answer for you before we end the call.

Rita Maldonado: Great, so picking up on Page 16 with the Staffing Plan. Here you need to include bio sketches for each of your personnel and include these for the senior or key personnel. And you can base the bio sketch on the NIH format that's used. And I encourage you to limit it to about two pages for each person.

> The principle investigator, Bruce already mentioned, is the individual who's the primary person responsible for the technical, programmatic, and

administrative aspects of the grant. They are the day-to-day manager of the

grant.

So when you're picking the principle investigator be sure that it's someone who not only has the skills to carry that task out but also the time. You don't want to be in a place where it's somebody who's just so busy in their other responsibilities that they just can't commit to this project. So be sure to think about that.

The principle investigator should be - have the skills of either designing and implementing interventions for increasing deceased organ donations or living donation if you're focusing on that or the skills and experience in the design of conduct and evaluation studies in the area of social behavioral intervention.

There - if you have a special situation where the PI is not employed by the applicant institution on the top of Page 17, you'll see information regarding that.

The principle researcher or evaluator is the person who is the primary - primarily responsible for the design of the project methodology and should have expertise in social and behavioral research. You'll see that that can - does overlap somewhat with the second option under the PI category.

And we're aware of that and that's okay. If you do have the principle researcher who's acting as the PI you do need to make sure that you have some sort of key staff member who has experience in organ donation interventions.

Great, you can read on your own about the assurances and certifications. Be sure that you include those items. Your project abstract is one page. It is key

because it is the document that would be shared with Congress or other individuals who are asking about your project so should be concise and clearly state all aspects of your project on one page. Be sure to include the information at the top of the abstract that's requested.

Great, the program narrative. We're finally to the heart of your application. I hope that you get to spend the bulk of your time writing that rather than working on the form. It is really the key thing that is focused on the most by the review committee. I want to assure you of that.

The - you need to - just to, real quick, your program narrative cannot exceed 25 pages so be sure to count those also before you submit. And if you are resubmitting an application that was not funded in a previous year we encourage you to include in your application dates of the resubmission.

And you can include information about the summary statement that you received from the previous review committee. You want to indicate the weaknesses that they referenced in the summary statement and then address how you are - how you've revised your application to address those weaknesses.

So I encourage you to do that. You're not required but sometimes we do have review committee members who have come back from a previous year and they may remember that you did submit it. They won't read - they won't have access to the previous applications or the previous summary statement so you will have to provide that information in your application.

Indicate which of the performance measures that you are proposing to address. The first two under deceased donation have to do with increasing either consent to become a donor or intent to become a donor and that depends

largely on state law. So if you're in a first-person consent state then you want to focus on the first and visa versa.

And if you are not in a first-person consent state and you are focusing - you have an intent registry then you should also be measuring whether or not people who have indicated their intent also told their family members of their decision. So you have that added burden. And again, here you want to indicate what the state law is in your area where your project's being carried out because the reviewers cannot bring in outside information such as that.

You can read the others on your own. If you are - want to address more than one performance measure you may, however, you have to be sure that you are clearly differentiating between the outcomes and the different components of your project and how they're addressing those different components or performance measures and keeping those things separate. So it does get a little bit trickier but you are welcome to do more than one.

Please follow the section headers and order that's described here in the FOA. It really is to your benefit to do so.

On to the Needs Assessment, here you want to include the needs for your community and the area where you'll be carrying out the project. And especially if you can include national data to sort of set the stage but the real focus should be on local data, even if it's unpublished. And you want to cite it of course, but to give a picture of the real needs in that specific area where you're proposing to work.

On to methodology, here you describe your intervention, indicate whether you're doing a replication or extension study. If you're doing one of those

two, again, you need to describe the initial study, justify why you want to replicate it, and describe any changes that you're proposing and why.

Describe theoretical foundation for your project, include any references if

necessary. Again, give more information about the target population that you're proposing, why you chose them and how you'll reach them, your

recruitment retention efforts, things like that. The intervention, describe

exactly what you're going to do. And then your evaluation plan, how you're

going to measure.

The instruments, if possible, include those as attachments, that's always a

good thing to do. Give as much information as you can in the application.

Page 21, include a work plan. There you want to include - this would be a

timeline with - giving some indication of who's going to be completing what

tasks and at what times. And again, (unintelligible) chart is great for this and

you can include the chart as an attachment, just reference it in your narrative.

Resolution of challenges is important because here it will show that your team

is able to work together so that when challenges, we expect each project will

have its own challenges, you will rise and your team will be able to adjust to

those in a way that's productive.

The evaluation technical support capacity is a brief summary about each key

personnel and - that's being supported on this grant and a description of why it

is that they're appropriate to carry out the task that they will be assigned. And

then the same is true under the organizational information, why those

organizations that are on the grants are appropriate for carrying it out.

Page 31

These would be things like, you know, that they are culturally sensitive to the

needs of the target population, that you have people on staff that speak the

languages of the target population, as well as technical capacity, things like

that.

Page 22, there's a list of all the attachments. Please be sure that you include

all of those.

Page 24 is where you'll find the funding restrictions I mentioned before.

Page 25, the other submission requirements has to do with the DUNS number.

Please be sure to review those and get started on those immediately.

Bruce Holmes:

Rita?

Rita Maldonado: Yes.

Bruce Holmes:

Just a quick note on that, that was a perfect place to jump in regarding the

DUNS number, I did research that and the consensus is that on Page 15 that

each contractor must provide the grantee with their DUNS number and be

registered in the central contractor registration.

Rita Maldonado: Great, one of the things that I've been told is that one of the reasons that a

grant will not go through the system is because an incorrect DUNS number

was submitted. So be sure that you have the correct number when you're

submitting your grant.

Bruce Holmes:

And just a reiteration on this thing so that everyone's clear, there is no space

to put a DUNS number for the contractor consortium or sub-awardee, that

information should be provided to the applicants at the time of - if it's

requested. There is no place to put the contractor/consortium/consortia member's DUNS number or CCR number in the application itself. And it's not required there but it must be reported to the grantee, the fiduciary responsible office.

Rita Maldonado: Okay, I want to go through real quick - and I know we're over time, but the review criteria. But before I go into that, on Page 28 it describes the review process. And I think this is really important for you to understand.

> When you submit your grant application it comes in through Grants.gov and it's sent on to the offices within HRSA where the initial eligibility review is made. And during that eligibility review we check for page limits, check that all required forms are included, and that you fall within the eligibility rules.

So those funding restrictions that are mentioned on Page 24, that you don't fall within any of those funding restrictions, and including promoting living donations for instance.

If it is deemed eligible it is sent on to the review committee and the review committee is made up of your peers, people who work outside of the federal government. And they are each given the application. Three individuals are assigned your application. For this program it is two researchers and one donation expert. Each of those will review it on their own. They write a summary statement, which is the strengths and weaknesses, and then they score your application.

The full committee comes together and they discuss each application individually. And they go through, they talk about why they - what the strengths and weaknesses were, and they discuss it. They - people who weren't assigned it, they ask questions.

Page 33

And eventually they come up with the summary statement which eventually

gets sent to you then the fully committee votes. They - sorry, they don't vote.

They score, again, your application each on their own and the scores are then

complied and then sent to us.

We then go through and we award based specifically on the score and go

straight down the line until the funds have run out. So I think it's important for

you to understand that and then we can go through on Page 26. And here you

see the review criteria.

And this is what is given to the reviewers for them to base their score of your

application on. And so I think it's important that you spend some time looking

at the review criteria, make sure that you address every item in here in your

application because that is what the reviewers will be looking for.

You'll also see that each criterion relates back to the program narrative

sections. They're listed right here so you can see exactly where they relate

back to. So you'll want to just double check, use this as a check list, and make

sure you're (unintelligible) every single thing.

Great, Page 28, as I mentioned, if you -- whether or not your application is

awarded you will receive a summary statement and that will include all of the

strengths and weaknesses that the objective review committee listed for your

application. So be sure to review that when you receive it. And that will come

out after the first announcements are made on the awards so it may be as late

as September of 2012.

On Page 30 there's a list of reporting requirements so if you do receive an

award, here you can exactly what will be required of you.

Page 34

And then on the bottom of Page 31 you'll see there's contact information

there.

Do we have any questions? Great, well, I'll take that to mean that you're all

ready to go and apply but, again, if you have any questions as you're working

on your application please feel free to contact me at any time either by email

or phone.

Thank you all very much.

END