>> I thank you very much for being here James, come on up. We also want to thank and give credit to Mr. John Hamill from the National Institute on Drug Abuse, who developed our model PowerPoint presentation for contracting officers and James is going to use that as background.

>> Thank you Diana. My name is James Quinn. I'm the chief contracting officer of NICHD/NIH. When I do these presentations, what I try to describe to you operationally is how an NIH R&D shop works and then I will give you my suggestions. I think of how small businesses, 8(a)'s and HUBZone companies might best avail themselves of the Federal procurement process is to identify requirements, to win requirements, to learn from the process so they might compete better for future requirements. Just by way of background, I had worked previously in the government as an attorney—an enforcement attorney and a cost auditor, but I spent my last 16 years in HHS, working at the department level and other OPDIVs and the NIH as a contract specialist, contract officer, chief CO, procurement analyst, so having worked in a lot of different places in the department, I have some perspectives that kind of transcend my own individual office, and then to the extent that I might be able to give you any information that might assist you there, I'd be happy to address your questions. The way our office works is we only issue solicitations for FAR part 15 negotiated procurements. We don't do part 12 commercial, we don't do part 13 simplified acquisition. Diana had asked me to speak to this and so it's a convenient place to kind of detour. We do have a requirement in our office—the office that I'd worked in previously—we were kind of a soup-to-nuts shop that did everything from part 12 to part 13 and part 15, BPA purchase orders, GWAC [spelled phonetically], schedules, impact cards, negotiated permits, sealed bids—everything, and so I was familiar with the part 12 concept of commercial contracting. So, we actually had a buy that was very appropriate for commercial contracting, but since we can't do that ourselves, we had to go to another office at the NIH. Our options then were—and again Diana, if I'm incorrect, please feel free to speak up—but we were to go to OLAO, which is where Cole works, or to use one of the NIH's many service centers, like the Cancer Institute; Heart, Lung & Blood, that could do that kind of work for us. But, basically we do negotiated procurements, but it's a bit disingenuous to suggest that we only do R&D. The fact of the matter is we do a lot of things that are in support of R&D, although the methodology that we use for acquiring those services and supplies is largely very similar with respect to the advertising, competing, negotiating, and award of those contracts. We do a variety of things including a lot of work with coordinating centers, data coordinating centers, clinical coordinating centers and statistical coordinating centers. Almost all of our research efforts for clinical research involve having a coordinating center that will serve as a central site for those areas. We also do a lot of work in data analysis, then a lot of things that are kind of considered support things, like communications buys, marketing buys, and many of those things are automatically kind of flagged, for either possibly a small business set-aside, or an 8(a) set aside. I don't know how much—I was not here when Bruce Simons-Morton spoke to this, and if you already got into that, I won't be redundant, but we will work with Diane's office, look at the e-PIC, look at the next code, use market surveys to determine whether something should be a small business set-aside or an 8(a) set aside. One of the things—and we do work for Dr. Simons-Morton, who is, interestingly, both an intramural and an extramural

researcher so we do his large R&D contracts. One of the things that he, no doubt, spoke to, is his role as a project officer on the R&D side. There really isn't much opportunity for you to market yourself to him. The rules of engagement in Federal procurements for negotiated requirements are such that by the time that we put a solicitation on the street, which of course we now do through FedBizOpps, unlike in the old days when we announced them in the Commerce Business Daily, and issued them in hard copy and that sort of thing, we don't even identify the project officer in that solicitation. We only identify the contracting officer, because under the rules of engagement, your only contact, really, through the award phase is with the contracting officer. So our situation is a little bit different than on this part 13 area that Cole's in with purchase orders and BPA's, where vendors actually have a chance to interact with the programs and demonstrate their capabilities. To the extent that we do that is largely, I think, with some of the 8(a)'s that we do—both the sole source 8(a)'s under $3 million and the competitive 8(a)'s over $3 million, we like—well of course, it's limited on the competitors where we issue solicitations, but we do like to have oral presentations from those organizations. The programs and the contracting officers find that very beneficial. I would like to also suggest, and I'm sure Diane, Stanley and Annette have already done that, you should really avail yourself of the NIH Small Business web page and take the advice that they've given you to good stead. We've had some very interesting things happen with 100% small business set-asides and 8(a) set-asides. I think that the mind set of most program people—that many years ago when you started talking set-aside, a lot of project officers got very queasy. I think that to the extent that there was ever a stigma has pretty much since passed, but occasionally it is the case that we'll go to a project officer and say, "This has definitely got to be a 100% small business set-aside" or "This is in the 8(a) program, it's got to stay in the 8(a) program," and we'll go through the mechanics of that, whether it's market surveys, working with Diana's office. We had one requirement that, for example, had been in the 8(a) program since time and memoriam and the program people kept saying, "Well, we've had all this technical migration," whatever that is. "It's not the same thing," you know, "what we bought in 1982 isn't the same thing we need to buy in 2002." We need to get it out of 8(a) and we worked with Diana's office, looked at the statement of work and it was pretty much—actually I think it actually went to the point where it went to the Small Business Administration and they looked at it and said, "No, it's the same thing, essentially." There's certainly every expectation that you're going to have two or more very highly qualified 8(a) companies. It's a point in fact that we wound up getting a new 8(a) company that's just been excellent. So I think to the extent that—it's kind of funny because now that the government people are in the position where, with all the A-76 and talk of constricting certain activities and merging certain activities and stuff like that, a lot of government people are fairly, very embattled and so it's kind of funny because we'd always get this feedback from small businesses that there's all these things in the marketplace that are enforced right now to hurt small business, like the proliferation of GWAC's and the ability of the government to go to some of these schedules and bypass the traditional small business venues and so I think that everybody's in this era of doing more with less and competing for different requirements, and we're certainly sympathetic to that, but I must say, almost every place I've ever worked in HHS, there's very much a concerted effort to properly identify actions as small business set-asides or 8(a)'s, as appropriate. I once worked at an HHS OPDIV that did $115 million a

year and 63% of our prime contract dollars either went to small businesses or 8(a)'s or HUBZone's and that's the prime contract dollars, and I think, even now, as I look at what we're doing, even though it might not be some of the sexier R&D stuff in terms of the support stuff that we do, about 40% of our new awards this year will either be small business set-asides or 8(a)'s. Just to discuss the process with you a little bit. Nowadays you will usually see—a solicitation will be advertised and issued concurrently in FedBizOpps electronically. For those of you who've been around for a long time, you remember it would be announced in the Commerce Business Daily and you'd announce that the RFP would be issued at some point—15 days thereafter or whatever. They're now done concurrently and most requirements are on the street for 45 or 60 days. We have some requirements now under the Best Pharmaceuticals for Children Act, which are very complex pharmacological efficacy trials that are going to be on the street for 90 days. The proposals come in; NIH has a requirement of title 42 of the United States code that for R&D requirements, not less than 75% of the reviewers through the ad hoc peer review process have to be non-government people. So we have divisions of scientific review that bring in distinguished persons with subject matter expertise to review our proposals and at least 75% of those persons must be non-governmental persons. Almost everywhere else, interestingly enough, almost anywhere else, you are competing for requirement in HHS, whether it's FDA, HERSA, SAMSA, CDC, ARC, ACR, Indian Health Services—anywhere—program support center, that requirement is not incumbent on them so they might convene, for example, 4 or 5 government employees to review those proposals. I rather like that, really, I think, in some regards because I think that to the extent that with regard to potential for things like protest and debriefings, the ad hoc process kind of offers a layer of independence with respect to technical reviewer proposals where it's not, you know, the project officer likes Schmekman [spelled phonetically] Institutes. If they're going to go to Schmekman Institute. If Schmekman doesn't score high enough and get a highly rated, successful technical proposal, they're just not going to be in the competitive range so I think it makes our job a little easier in that regard. I think it does, truthfully, insure a level of fairness to offers, not at all to suggest that program people would be less than fair, but it does have an independent review process. We generally do cost and price analysis on our own, but NIH has the resources in the division of fiscal advisory services to do cost and price analysis of your proposals. We also conduct past performance on proposals, as appropriate, something that some of you might be familiar with, particularly if you are an 8(a) concern. All of our full and open competitions have a provision in them for small and disadvantaged business participation, which is to say that offers must, in their subcontracting plans, show us how they propose to use small and disadvantaged businesses should they get the contract, and that's actually an evaluation criteria. When that first came in a few years ago, I really thought we'd see more teaming of major universities and large for-profits with 8(a)'s to take advantage of that, but there's still some anecdotal evidence that suggests the [unintelligible] policies work. I'm not sure that we're seeing the teaming to the level that was anticipated, but the proposals are reviewed for all those things. Negotiations are [unintelligible] with those in the competitive range and of course awards are made if—the decision by which the awards are made is detailed in the section M of the solicitation. You'll usually typically see language to the effect that, for an NIH R&D solicitation, we'll say that the award will be based—technical considerations will be

paramount in the award of this contract in the event that two or more of technical proposals are substantially equivalent—cost and other considerations including past performance and small and disadvantaged business participation will be considered, in any event, the government reserves the right to make award to the offer that provides the best value to the government, whatever that means—sufficiently vague, I think, that they can award to anybody as long as they really have the best technical proposal. One thing that I always bring up in here is my suggestion based on having done this for many years. There's a couple things that small businesses might want to do in this area. One is, I do think that teaming is important. If you are competing for requirements, whether those requirements are—if it's a competitive procurement, whether you're competing for a requirement that's full and open, whether it was a set-aside, if you are an unsuccessful offerer, the government will inform you formally at such time that you are no longer under consideration, whether your original proposal was determined to be unsatisfactory or technically unacceptable, or if you were considered technically acceptable and went through negotiations but did not receive the award, you will be notified formally, in writing, in a timely fashion, which, of course, among other things preserves your right to file a protest with the agency or with GAO. We'll also advise you of your rights to get a debriefing. It's interesting that two years—this is my third stint at NIH. I came from an agency at HHS that does a lot more work with commercials—when you're doing R&D, you do a lot of work with educationals, but educationals, a lot of times they don't get a contract. That's fine, I'll move on and I'll compete for the next one. Commercial organizations, whether they're large or small, don't walk away so quickly; their bottom lines are different. I've noticed that, in my office at NIH, we do very few face-to-face debriefings and I think, if I were an unsuccessful offer, particularly if I was a new or emerging organization or organization just getting started with an interest in a particular subject matter area and really wanted to get better and really wanted to be in a position to compete down the road, I would avail myself of the opportunity to take a debriefing. A lot of people take debriefings with the government because they want to go in and make sure that they were treated fairly. Was my proposal evaluated fairly, was I dealt with fairly, was the award on the up and up, was I treated fairly vis-à-vis the other offers. That's fine, I can understand that motivation. If you think you wrote a great proposal, you spent a lot of money, you can't imagine how someone could have done better, well, debriefing shows you how because your proposal will be compared only to one proposal and that is the successful offer. But, I think you should also take it as an opportunity to go in there—generally, the contracting officer of record, project officer will be in there, they'll apprise you of what your strengths and weaknesses were, and it's an opportunity to really learn. Commercial organizations do that more so, I think, than educationals and I think it's a process well worth taking advantage of.

>> (low audio)

>> Okay, I'm sorry.

>> (low audio)

>> No. Is it about debriefings, or...

>> (low audio)

>> Well, what was that then?

>> (low audio)

>> Okay, the question is, in what detail do you get too involved in the debriefings. I'll tell you what, I've been in debriefings that have lasted 4 and 5 hours, if that will answer your question. The vast majority don't last that long, but how many of you, by the way, do submit proposals for formal part 15 requirements? Okay. Generally, when you go to section M they'll give you 4 or 5 sections, usually it's like, where were you— evaluate direct labor, understanding the requirement, technical approach, direct labor, organizational, experience, and etc. Then they may have sub-elements and I've been involved particularly—say a multi-million dollar commercial activity, like marketing, technical assistance, communications, where you might actually score sub-elements. We don't actually do that as much at NIH as they've done at some other places, but let's just say, you have 4 elements worth 25 each and the first one is understanding the requirement and you might have 3 or 4 sub-elements that are weighted 6 or 7 points and I've been in debriefings where it literally becomes grist for the mill, where people are tabbing pages in the proposal and saying, "Gee, how did we only get 5 out of 7 here when you said 'understanding the executive branch of the government' and you gave us 5 out of 7 and we had Bill Clinton proposed as a," you know. "How did I only get 5 out of 7?" It becomes that kind of thing and so when you have a 5 or 10 or 15 million dollar contract or even less than that, if it becomes the case that you're essentially being compared with the successful offer and you want to know because basically, your right to file a protest is told by the debriefing period. If you have x number of days to file a protest, that period is staid while you're going through the debriefing process. I mean, I have been in debriefings before where the company was so well prepared. It was actually a very large 100% small business set-aside for technical assistance, and one company came in so well-prepared and tore the government—it wasn't the NIH, by the way, I'll be quick to say that—but basically, discredited the government technical review process to the point that the government went back and re-reviewed those same proposals. Because you know if you're submitting a technical proposal with a depth of the Manhattan directory, and things get missed, but those are your rights. There's nothing so disconcerting to a contracting officer as to come in and see a $500 an hour guy from Hogan and Hartson in the corner. Somewhere along the line, he's going to earn that money, and for 37-cents, you're engaged, so I'm a huge proponent of using the debriefing process. If you have questions when the solicitation appears in FedBizOpps, you are given the contact point for the contracting officer and usually nowadays they also have an email address. I thought this solicitation was very clean and I would venture to say we have probably done three amendments addressing about 20 substantive questions that came in—and this is a 100% small business set aside, so I think this also goes to the issue of people who are under the impression that there's not a very high level of sophistication in that area. One of the questions that—somebody kind of asked the question for example they stated, their preference, for example, in the direct labor. They said, "You must provide a management

analyst with a business or business-related degree." And so--not that it's a go, no-go criteria, but you may score higher or lower. And so someone wrote in and says, "What's a business related degree?" That's a good question. Is Math one? Maybe yes. Is sociology? No. So it made us go back and define our terms, and because it's like anything else in this litigious era, you never know which is the bullet out there with your name on it, it's best for us—I mean, that's one good thing that comes out of all these things, is that the more work you do on the front end, the less you do on the back end. You want to write a really good requirement, no project—well, project officers, are somewhat immune to this, but not the C.O. You want to sit down and be laboriously going through 20 questions about your solicitation, it's best to go through—but I'm sure many of you see some really awful solicitations out there sometime, but you know, the reason why they give you the name and the email address of the contracting officer is if you have a legitimate question, if you don't understand the requirement, ask the question. Do we like seeing those things come in? No, but you want to know that you have the best requirement out there. I just want to see if I have any other—oh—pardon?

>> (low audio)

>> Diana said tips on marketing. There's really not much you can do, I think, in terms of really marketing in the sense of lobbying our office, our program people, but another tip I always offer is, and like I said, I literally met with my branch this morning because if you all ever read the paper, the government's going through all these things now where they're talking about consolidating activities and all those kinds of stuff, and so you meet periodically to discuss how real these things are and that sort of thing. It's—the government is doing more with less. The staffing is not sufficient in many places and so one of the effects of that is that people, whether it's really the best way to go or not, to the extent that it's lawful and appropriate, people will look to schedules. I have to tell you there are some great schedules out there. When I was at another OPDIV in HHS, we bought a requirement one time for a huge program. It's a—some of you might be familiar with the Ricky Ray. Ricky Ray was a young boy who contracted AIDS through—he was a hemophiliac who contracted AIDS through a transfusion and we set up a compassion payment program. It wasn't a compensation program, it wasn't a legal program for paying claims from administrative or legal adjudications, it was literally a compassion payment program, but we needed to be in a position where we could set up an entire program for processing 10's of thousands of requests from around the country, and we needed to be able to have a component of this that was something that—and I don't mean this in a pejorative or dismissive fashion when I say, you know, a classic 8(a) scenario where you have someone who like provides application, receipt, processing, set up a database, stamp 'em in, that kind of stuff. We needed that part, but we also needed to have legal expertise for people to look at the applications for their legal sufficiency, we needed to have M.D.'s look at the applications for medical sufficiency, and we needed to set up review panels to go through all these applications and we needed one contractor to do it. Somebody would say, "That's bundling." Somebody might say that, but they weren't looking when we did it, but the point was we were able to go to the GSA MOBUS schedule and find three organizations who were able to do all of the stuff from receipt application through medical and legal reviews and provide it to us at 50-cent on

the dollar from our government cost estimate and we did that in 2 months. I mean that's just unbelievable, and those are things that are out there. And so, even at NIH, I don't know how much Diana told you, but they have the rooftop schedule. That's not done out of my institute, that's done out of OLAO, and quite frankly, I don't know the exact mechanism for getting on rooftop, but—

>> (low audio)

>> Yeah, it was re-competed. They also had SIOPS—

>> (low audio)

>> [unintelligible], but if you can get—GSA has a program, for example, called MOBUS, which you don't compete for, you apply for and you're considered eligible and you're added to it and they do what are called limited competitions after exclusions of sources. Once you're on there, someone can go there and say, "Give me these 3 or 4 and I'm going to compete it amongst those 3 or 4." There are some tremendous ones. Department of Interior has one, Commerce has one, COMET is the 8(a)—is an excellent one—and I think to the extent you can get on schedules, the reality is, I think, that more and more even for requirements that are over $100,000, people will—we can't do that for our R&D stuff, at least not yet, but for support type stuff, there's schedules for marketing, for technical assistance, communications, almost anything you can imagine. I would really encourage you to look into those. I think that increasingly, those will be the wave of the future. Yes?

>> (low audio)

>> It's a really an interesting question. Part of the problem that we have, and there's some people that in here from NIDA who are contract people, so--plus we're videotaping so I really have to be... At HHS it's a color of money issue. We are essentially a research institution, and so, what we have is moneys that are 842 moneys that are only supposed to be used for research and development. Those contracts—those moneys can only be spent on requirements that go through all of the things that are attendant to that—concept review, peer review, that sort of thing. So, to the extent that—then other offices, like the service centers, they have 832 money, which is just, like intramural money that you can use on anything. So, as long as NIH, for example, in the research arena has this color of money issue, we pretty much will always spend our research money in that fashion. What happens with the 832 money is a little different. What also institutes can sometimes do, and again, I've got to be careful how I state this because I'm not a budget officer, but they can sometimes re-can money within their institute within a very limited range. The fine line between intramural and extramural is hard to say, but it just seems to me there are things—I can remember in Federal contracts when you had to advertise, I think everything over $10,000 and now that's $25,000. I mean and simplified acquisition levels, like Cole said is a $100,000. Well, the last time I looked it was a lot of money. You can do purchase orders—purchase orders are just—I mean it's unbelievable. I mean that's a lot of money that can be moved in a fairly informal fashion, as far as I'm

concerned. I've never been comfortable working in that area. I mean that's a lot of money and I think Cole's point was well taken. If you're just starting out, don't sneeze at purchase orders. A lot of places—like if you look around the government, they are doing blanket purchase agreements, programmatic blanket purchase agreements, which the BPA itself isn't actually a contract, it's just an ordering mechanism with terms, the individual calls it a contract. Like VA has one and I think the individual calls can be up to $500,000 or a million. I've had IDIQ contracts for conference and logistic support where you can do delivery orders. The individual delivery orders can be up for like 2 years or $2 million, so the stakes are getting higher and people are buying more and more with single buys. So, it goes kind of to the more than less. In other words, if you have a bunch of 8(a) contracts for conference and logistic support, I won't—this is certainly Diane's area, say what's bundling and what isn't—if I know that I'm going to have the exact same conference being held twice a year for the next three years, am I really going to sit there and do six separate actions, or am I going to do a 3-year award with somebody so I can have the—once my program's continuity of services, they want those same people, so that means instead of six people getting opportunity, one person's going to get a really nice contract.

>> (low audio)

>> Yeah, I mean—not so much for an individual requirement, but for example we had a situation recently where there was a very, very outstanding 8(a) company—I mean, they just have a—their capability statement is tremendous; they do a lot of different support things and where I worked previously, I had wanted to do some work with them and I left before--but an opportunity came up recently where we might be able to have them compete for doing some workshop conference work, and so, through Diane's office I reconnected with this individual and she sent me her capability statements. And at such time that we go to proceed with this procurement someone from my staff will actually meet with her and they'll have a chance to do a capability presentation, but there's not a corollary for that like on major clinical studies. I mean, it's just not there.

>> (low audio)

>> Well, OK I tell you what, you can actually—there are provisions for unsolicited proposals and they're defined in the FAR and occasionally research and development actions are funded, but you could actually--it has to be truly unsolicited. It has to be unique and innovative. The surest way to get an unsolicited proposal killed—and I've actually had people send these in—if you go to the FAR and the HSAR, there was a reference on one of these things about some of the acquisition regulations that we live with that, that we go by and they have provisions in there for unsolicited proposals, and if you send in a proposal and it truly is unsolicited, it's unique and innovative, we do a review of the proposal, we can actually go to our institute director and someone from that program area would say, "This is something we want to fund," and we can issue you a sole-source solicitation and actually, that happens sometimes—not often, but sometimes. Now it's very difficult because you're competing for dollars, but the standards are set out in the FAR and the HSAR. It has to be unique, it has to be innovative, it has to not relate

to a current RFP. For example, if we put something out there on—we do a lot of, in addition to biomedical stuff we do a lot of behavioral sciences stuff, and so we have things on family change, like, how have things going on with two parents working and things like that, how has that affected children in these family change studies. Well, we put out a RFP for family change and two weeks later you write out a letter and say, "I had this idea for a requirement on family change." Well, it specifically says in the regulations it can't relate to a current requirement. What often happens, and it's really kind of unfortunate also, is that someone will have this germ of an idea and they'll talk to a project officer and [unintelligible] based on a conversation with Dr. Schmekman from your epidemiology office, we're submitting the following unsolicited proposal. Well, your conversation with Dr. Schmekman probably made it no longer unsolicited. Our sense might be then that he directed you to do that. We look into those kinds of things, but there are provisions in there if you have this unbelievable idea and you think the government is not—I mean, it happens all the time. Sometimes people will send things to, particularly in our area we do things related to maternal health, child health, things like that. Someone will send that same requirement over to—at the Health Resources Services Administration, they have a Maternal Child Health Bureau. They might send it to both places, just a shotgun approach--will somebody fund this?

>> (low audio)

>> Well, you could write to the contracts office, usually will go through—

>> (low audio)

>> Yeah, sometimes people will literally write to the institute director. Of course he'll just send it down to us, but there are provisions in the FAR for that. If you think that you have an area that's a hot area that the government has not been funding appropriately, then you can try to initiate something, which is good. Also we have—I guess you should—have you told them about the SBIR program? Okay, I think that's a very—that's found money for us because it comes out of a different pot and so I think you should also watch for some of the SBIR initiatives. Anymore questions?

>> Wasn't he terrific? Thank you James.

>> (applause)