

The National Academies

Federal Demonstration Partnership

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NANCY WRAY: And let's get started. I want to wish you all a happy New Year. It's good to see so many faces. And I want to thank the Washingtonians for allowing us this wonderful spring weather. This is normally the meeting where we're enjoying sunshine in a warmer climate, and so I think Washington tried to provide that for us in the absence of going to another location, so thank you very much. And in fact, I think it's going to be really springy today.

I have a couple of announcements I'd like to make, and the first and foremost is to announce our new executive director of the FDP. David, would you come up? I'm very pleased to announce that David Wright is our new executive director and many of you may know David already. He's been involved with FDP, has co-chaired the ERA Committee from the federal side. We stole him from NIH. Thank you very much, Joe Ellis. And we are very pleased to have him. David has university experience as well as federal, so I think he's a wonderful asset. So let's all give David a warm welcome. So any issues with the meeting, see this man.

Okay. The second announcement is we are going to go offsite for the May meeting. And I'd like to have Carol Zuiches come up and tell us about the meeting. It's going to be hosted by the University of Washington in Seattle.

CAROL ZUICHES: Good morning. And I'm extremely pleased that everyone is being invited to Seattle for the May meeting. That's on the 22nd and the 23rd of May, so expect great weather. Right now we're doing 24 days of rain and counting, but that will be over by that time. It'll be at the Renaissance Marriott, which is downtown, and so within walking distance of just about everything.

The rate is \$189 a night. The important thing is that you must register for this one early. And I'm told by Edvin Hernandez, who did the work on the negotiations, that this group tends to register late, and that will really be problematic. So registration, try to get it done before April 6th. The rate is guaranteed from Saturday through Tuesday if you decide to come a little bit early. The website for all the information and the registration information will go up next week, late next week probably.

And generally, we hope that, this is a great hotel. It has great conference space. At this point, as you can imagine, we were a little bit crunched as far as opportunities where we had both the conference space and the room space, but this one is really a great option. So we're looking forward to you being in Seattle. Please come, enjoy, and thank you.

NANCY WRAY: Thank you, Carol. I also understand that there's, maybe some good rates for flights right now, so you may want to take a look at that. The other piece of information, as you may know, you've gone through your agenda and it looks a little different from the last time. You know, we don't want to keep things too standard. We like to keep them jumping. And I'm going to have Joe really kind of articulate our thoughts on why we're changing the agenda again, and really would appreciate your feedback of how you think that this change is beneficial or not to the group.

JOE KONSTAN: So it's really simple. We're trying to experiment with what would happen if a grants policy manual changed on a quarterly basis. No. It's a secret demonstration. No. That's not why we're changing the agenda. As you've seen over the past several meetings, we've been doing things, trying to maximize the valuable time that people spend here, and looking at the sessions where we see that there are not quite as many people staying and looking, how can we get that information out to people in other ways.

The biggest two changes you'll see that were intentional this time, and I'll come back to unintentional in a minute, are the change in the timing of the federal agency reports and putting that up in a more prominent position. We've heard from a number of people that it would be really useful to not hear what's happening and then have everybody leave and have no chance to talk to the federal agency representatives.

Plus a number of people have said, hey, I've only been coming here four or five years, I don't know who all these federal agency representatives are, it would be nice to be able to corner them after a report and say, by the way, can you tell me about this or that. And I think our federal agency representatives willingly or otherwise are going along with that idea. By putting them early, we have that opportunity to give you a chance to find out what's going on in time to react, ask questions, comment.

Second, the long tradition of committee reports at the end, we've noticed, and I'm sure you've noticed too, if you're among the few people who are here at the very end, that not only do a number of people depart right before the committee reports, but that a number of people continue to depart, delicately looking like if they don't look at us we don't see them, in the middle of those reports, and we checked first with the airports and we found out, no, there are flights all day long, that wasn't the main reason, and we therefore said maybe people would rather read these rather than hear them.

And so what we're going to try is to get the same committee reports, committee chairs already know this, that they're going to be expected to deliver a report, though it doesn't have to be PowerPoint since we're not going to do it up on the big screen. We will put them up on our website and we will be sending out to you a newsletter summary of the highlights.

And, you know, each committee can help us by identifying in some cases things that are particularly highlight, in other cases we'll say, yeah, everything is just business as usual, things are wonderful, read the details at this link on the web. As Nancy said, we don't know that this is going to be better. We want to hear from you. We'll be asking you for your feedback on the meeting, and the more we hear, the more we will keep things the same or change, depending on what you say.

In the spirit of change, there are also some unintentional changes. Due to a scheduling conflict with one of our speakers, we're swapping two sessions. In the middle of this session this morning we were going to have Belinda Seto talking to us about research business models activity in research conflict of interest. Due to a conflict of scheduling, that's going to be moved to tomorrow morning, and we're moving the preliminary results of the faculty PI administrative burden survey to this morning at that time. Since you were going to be here for both of them, that's not going to affect you very much. If you were thinking that, oh, good, I can cut out early, well, you probably don't want to anymore. I think that's all we have. Thank you.

NANCY WRAY: As I said, the FDP continues to evolve. And one of the other changes we have looked at or one of the other areas we have looked at for change is the administrative processing group that is a very large activity encompassing pre-award and post-award and financial and audit and etc., and we thought that it really might be more efficient to break it apart.

And so what we have decided to do is to have a research administrative component, and Gunta Lidars has agreed to head this group and we will be looking for a federal co-chair of this group. And that Beth Mora and Debbie Rafi will continue to head up the financial and audit and costing side of the issues, and then we think that this will be a little more workable and be able to address the various needs. So I wanted to let you know of this change. And we will be continually working between meetings on the organization and how this will work.

Another reminder, the Membership Committee sent out a notice that institutional reports are due, I believe, by the end of this month. They're online. It's a requirement of the memorandum of agreement that we all signed as institutions to do these reports. Please get online and complete them so that we won't have to send you interesting reminders and then announce your names at future meetings. So we look forward to this information. It is really important for us to have, and so I would please urge you to get online and do those reports if you have not.

Okay. Another activity that the FDP has taken on is to, as I have mentioned before, is to form a strategic planning committee. And our committee met for a two-day retreat in November, and Dick Seligman is the chair of this group, and he's going to give you a report from this committee and some thoughts of where we are going. Dick.

DICK SELIGMAN: Thank you, Nancy. Good morning. That was very weak. Good morning, ladies and gentlemen. Oh, that sounds much better, much better. Last spring, our chair, Nancy Wray, appointed a strategic planning committee to take a look at the future of the FDP. And among those who were appointed to the committee were Susan Braunhut, Joe Ellis, Jean Feldman, John Fini, Pat Fitzgerald, Ken Forstmeier, Geoff Grant, Jason Hitchcock, Joe Konstan, Merrilea Mayo, Vijaya Melnick, Jack Puzak, Andy Rudczynski, Susan Sedwick, and Nancy Wray. Thank you for your kind attention. That is not the full report yet.

So as Nancy mentioned, we had our first meeting in the fall. And we had the benefit of a professional facilitator there to keep us on track and focused. And we began by taking a look at the past activities of the FDP and tried to identify places where we had been successful and perhaps places where we had been less successful.

And among the key successes of the FDP, we identified the following. First, the expanded authorities and the creation of the FDP terms and conditions. Second, the standard sub-award agreement and the variations on that that you'll be hearing more about later. Third, the metamorphosis of the non-competing continuation application into what we now see as an annual progress report. And several of our federal sponsors have made this metamorphosis and thereby having reduced a considerable amount of workload on the part of many of us.

But beyond the demonstrations, the FDP has become a unique gathering place where federal agency program and administrative officials work directly and collaboratively with university researchers and administrators. We also found that the FDP has become recognized as a forum for bringing up issues that impact the research community.

So what have been our shortcomings, where have we not quite hit the mark? Well, first of all, we haven't initiated any new demonstrations lately. We haven't fully engaged the inspector general and audit communities in our work. We've become somewhat of a default forum for some issues and topics that really are beyond our main focus. And finally, we haven't been terribly anxious to take risks, to stick our necks out.

From this look to the past, we turn to a consideration of the future of the FDP. And if we are successful, future generations should be able to look back and find that researchers are doing science, not administration, that successful demonstrations have resulted in improved administrative processes for research grants, that collaboration between federal granting agencies and grantee institutions has been improved, and that accountability and stewardship are shared values of all members of the partnership.

Geoff Grant, who was one of the founding members of the FDP, put it very well in our planning meeting when he said, you know, the purpose of the FDP is to enhance science, to reduce administrative burden, to facilitate collaboration among the various constituencies, to improve grants administration. And the reason for doing all of this, going back to the intent of the founding mothers and fathers of the FDP, the reason for doing all of this is to increase the productivity of researchers by minimizing the administrative obstacles that distract them from their primary mission.

The key elements of our vision for the future of the FDP include putting the rigor back in the FDP demonstrations, or as some of us would like to say, putting the D back in the FDP. Second, maintaining an effective process for collaboration, that is, enhancing the role of the FDP as a forum where members of this partnership can gather and exchange views and ideas. Third, engaging the active participation of diverse members, including both federal research agencies and grantee institutions. And finally, creating an effective structure to support the FDP's mission.

Although the Strategic Planning Committee began with a focus on recommending whether or not there ought to be a phase five of the FDP, and if so, how it might be different from phase four, before our first meeting ended, we had reached the very strong consensus that many of the changes that we had been discussing for phase five could actually be implemented much sooner. There's no reason to wait. With that in mind, the Strategic Planning Committee has made the following recommendations to the chairman and to the Executive Committee.

First, we recommended the formation of a task force on invigorating the demonstration process, or as I said earlier, putting the D back in the FDP. This group is

going to review, modify, and document the process for proposing, prioritizing, selecting, implementing, tracking, and evaluating demonstration projects. The outcome of this effort will be an FDP demonstration template that provides a framework within which demonstration projects can be created, implemented, and assessed.

And our chair has appointed the following individuals to serve on this task force. Andy Rudczynski of the University of Pennsylvania will chair the group, and he will be joined by Jack Puzak from the Environmental Protection Agency, Susan Sedwick from Oklahoma State University, and a faculty representative not yet identified.

SUSAN SEDWICK: I'm at Oklahoma.

DICK SELIGMAN: What did I say?

SUSAN SEDWICK: Oklahoma State.

DICK SELIGMAN: I humbly apologize. You are at the University of Oklahoma, not at Oklahoma State. In fact, you've never been at Oklahoma State. And after this, you will never want to go there. Our second recommendation was that Susan Sedwick move to Oklahoma State University.

Our second recommendation was the creation of a task force on assessing and recommending demonstration projects. This group is going to take the results of the work of the first task force that I mentioned and apply it to the currently existing, pending, and potential FDP demonstration projects. The task force will make recommendations for demonstrations to be undertaken in the remaining period of phase four and begin the process of making recommendations to be undertaken in phase five.

The specific membership of this task force has not yet been identified, but I believe that the members of the Executive Committee will take a leading role in performing this function. We were very big on recommending task forces, so there are two more that we've recommended, and neither one of them had anything whatsoever to do with Oklahoma State University.

First was a task force on engagement, and that's a polite way of saying seeking a champion for the FDP. The purpose of this task force will be to identify high-level champions in federal agencies and grantee institutions. And it's hoped that this group will identify the mechanisms and strategies to engage and gain support of one or more FDP champions.

And finally, we recommended the creation of a task force to take a look at the relationship between the FDP and the Government-Industry-University Research Roundtable, our host here at the National Academy of Sciences. And this group, this task force, will define and formalize the desired relationship between GUIRR and the FDP and will include an identification of some of the legal and financial aspects of the relationship.

It's somewhat ironic, given the nature of this organization, improvement of grants management, that our relationship with GUIRR has never been committed to writing. Maybe that's one of its great virtues. I don't know. But one of the results of this effort is going to be to make a somewhat more formal relationship between the FDP and GUIRR.

The Executive Committee of the FDP has endorsed the report of the Strategic Planning Committee that I've just summarized for you and has approved the creation of some of these task forces. So I believe that we are well on our way. We are going to convene again in May in Seattle, if it stops raining, and we'll have more to report at that time. If there are any questions, I would be happy to try to answer them. If not, thank you very much.

NANCY WRAY: Dick, would you like to comment on the recommendation to go forward or not . . .

DICK SELIGMAN: Yes, I would like to comment on that. Originally when I was asked to chair this committee, I thought that my assignment was to chair a committee that would examine the question should there be a phase five or should we be planning an appropriate memorial service for the FDP, it's done what it was created to do and it's now time to lay it to rest and go on to something else.

And I think that what became fairly clear very early on in the discussions of the Strategic Planning Committee is that, yes, there should be a phase five, and, no, we have not completed all of the tasks for which the FDP was first created. And the members of the committee left the meeting having sworn that there will always be an FDP. Thank you. Did you have another question?

NANCY WRAY: Thank you. No.

DICK SELIGMAN: Thank you.

NANCY WRAY: I think for the task force we will be drawing on members not just within the Strategic Planning group, but members of the FDP in total to staff some of these activities. If you are interested in any of the three that have been mentioned or we need a faculty member for the fourth, actually the task force is going to look at demonstration processes meeting today at noon in Room 250, and if we could have a faculty representative, that would be great.

The next part of our session we're going to go on to the federal updates. And I will be calling the agencies up to give their presentation. Most of them have them on the computer already. One of the things that came out of the Executive meeting yesterday and is a very, I got a very good suggestion and we will implement it in the future meetings, is part of the federal updates is that we would like a report from the RBM, the Research Business Models group, so they can update us on their activities as well.

And also that we get an update for the different GUIRR activities that are going on, that we might be interested in partnering in some of those activities. And those groups really have not made or have not been available for formal sort of updates, and I think the suggestion is an excellent one and for the May meeting we'll incorporate those into the federal updates. So at this time I'm going to turn them over, and the first agency we're going to call on is the Air Force Office of Scientific Research. Is Kathleen, yes.

KATHLEEN WETHERELL: Good morning. My name is Kathy Wetherell and I'm with the Air Force Office of Scientific Research. And I do not have a presentation to actually give. I just had two short items really that I wanted to tell you about. With our grants, we're in the process of changing the requirement for the performance report. The annual report we used to have due on 1 September of each year. We're changing that due date now back to the anniversary date of the grant.

We originally had changed it to 1 September because there was a need for the program managers to have the information for the fall reviews that they went through, and they've changed those meetings so it's no longer necessary. So we decided to go back to the annual date. We are only going to, right now we're planning to only change it in new awards. We're not going to go back and change anything that's in existence. We're just going to let those go through their regular process.

And the second item, we are in the process of finally doing a Grants.gov test and we're working with MIT. We have a professor there who's submitting a proposal for us right now. So once that process is completed and we can eliminate some of the bugs we have on our end, we hope to amend our BAA and request that proposals be submitted electronically through Grants.gov. That's all I have. Thank you. Any questions? Thank you.

NANCY WRAY: Thank you. Okay, the next agency, Army Medical Research and Material Command. Okay, it doesn't look like we have . . . Army Research Office. Kathryn. And would you please identify yourselves?

KATHRYN MCMANUS: Good morning. I'm Kathryn McManus from the Army Research Office. Actually I'm just here to represent the Army Research Office. I'm actually RDECOM. We're co-located with ARO. They're our prime customer. I've only got one slide. It's good to be back. I've been on a developmental assignment for the past year, so some of you may know me but haven't seen me in a long time, and that would be why. But I'm back now. Can I get the one slide? It's just one slide.

I just wanted to announce that the Army Research Office and RDECOM, ARO and ARL are going to transition to using iEdison. I know many of you are using iEdison already with other federal agencies, and we've been asked about it and didn't know anything about it until recently, so we've coordinated with NIH and they've made it available to us as well.

iEdison, or Interagency Edison, is a web-based system developed by NIH and then made available to other agencies that facilitates compliance with federal laws regarding intellectual property issues and the reporting of patents, inventions, licenses, disclosures. It'll replace all the paper-based systems, including eventually our DD 882. I believe there's a federal form, a federal standard form being developed that should be announced pretty soon in the federal register, which will also replace that, and patent applications and etc.

It allows our grantees to access the database in real time. It's a very secure system in that you only get access to your own organization's information. And you can upload data directly from your own system into iEdison. And since you can't do that and if you are doing that already, we ask that you go back for ARO and ARL and input data that should have been input years ago into iEdison. We've got quite a backlog in our

office that we're going to have to input if it's not otherwise input, and so we ask for your assistance in doing that. And that's it. Any questions?

PARTICIPANT: How many years back?

KATHRYN MCMANUS: Oh, boy. You don't want to know. Let's try 15. Yeah, a long time.

NANCY WRAY: So to clarify, you're asking the institutions to . . .

KATHRYN MCMANUS: Yeah, to input their invention disclosures, patent information, the information that you would have input had we been on iEdison earlier that you might have input via paper, because we've got a lot of paper. And right now our system doesn't upload into iEdison, so we would have to do it manually.

NANCY WRAY: And you would like us to do that for the past 15 years?

KATHRYN MCMANUS: As soon as possible. Yeah, let me get back to this. I'm glad you mentioned that. NIH is going to send e-mail blasts letting everybody know that ARO is now one of the authorized agencies to report the iEdison. You'll see that on their front web page. And it'll also be one of the choices for the drop-down to choose the agency.

And then ARO and ARL will also begin sending out letters notifying you that we're going to be using iEdison and we're going to put the language in our contracts and grants requiring you to use iEdison and probably even go back and modify some old grants and contracts to add that language. So, yeah, so I met with John Salzman just yesterday and we've got everything pretty well ironed out. And I would say no later than the 1st of February expect to start seeing the letter notifications and e-mail blasts. Thank you for that question.

NANCY WRAY: I guess I'm just thinking about the ability of the institutions, the burden there to go back 15 years for . . .

KATHRYN MCMANUS: No, no, no. I'm not, I'm just saying that we've got that sort of a backlog, but I'm asking, if you've got that information already in your system that can be uploaded, you know, it's just a matter of pushing a button and you send it, then please push that button and send it. I'm not asking you to go in and key in anything that's not already in your system.

NANCY WRAY: Okay. Thank you.

KATHRYN MCMANUS: Yeah, yeah. No, no. If you can upload it, you know, and it's already in your system, yeah. But I wouldn't ask you to do that. Any other questions?

NANCY WRAY: Thank you, Kathy.

KATHRYN MCMANUS: Thank you.

NANCY WRAY: Bob MacDonald, I believe you're going to do the Ag?

BOB MACDONALD: Good morning. For those of you still on West Coast time or perhaps a big groggy, I am not Louise Ebaugh. And so we will talk about that. Louise Ebaugh retired earlier this week after quite a notable career at CSREES. And we were sad for her loss, but we also celebrate who will be replacing her. We have made an offer, and Andrea Brandon of the Department of Health and Human Services has accepted that offer.

That is conditional upon approval from the Office of Personnel Management, which is standard for these types of positions. And that takes an undetermined amount of time, ranging from theoretically six weeks to usually somewhere between four and six months. So in the meantime, I am acting deputy administrator for the Office of Extramural Programs, and that's why I'm up here and I'm not wearing a skirt. I apologize.

And so the other thing I would like to talk about today, and then before turning over to Jason, who will give an update on electronic grants activities, is our expanded authorities demonstration, particularly that dealing with second no-cost extensions. So this was a demonstration that CSREES really initiated alone as a federal agency about a year ago to allow a second no-cost extension up to 12 months given the conditions that I won't bother to read for you, but for pretty much common sense, which basically follows the same lines as we've done now for quite some time.

For the first no-cost extension, it requires us to be notified within ten days of the approval. We had 24 participating institutions that worked with us on this demonstration. And we believe it to be quite successful. There were approximately 1,500 total no-cost extensions that we did during that time from these institutions. I'm sorry, total. No, for these institutions. I've been on this a week.

Forty of these were second no-cost extensions. That's 3 percent of the total. In other words, it is not a big backlog of the total amount, but it is notable. Only 3 of these 40 were denied, and all of those were because they were requesting for no-cost extensions beyond the term of the grant. And so that's really an education issue or a realization issue that needs to occur that I think can be easily overcome.

It should be also noted that these institutions had actually given us 84 second no-cost extensions, made requests for those. Only 40 of those were done through this where they self-approved in notifying us. The others were ones where they formally requested it in the traditional manner. And so there is opportunity, in fact, for greater use of this.

And so we have some recommendations that we'd like to present to the FDP and to consider for moving forward with this. One is to expand the participation of this to other institutions within the FDP and also to other FDP agencies. Again, we have found this to be tremendously successful. It's another way to alleviate some extra work, and so it's something we can move forward with.

And then we could also consider adopting this as new expanded authority, so we'd like to bring that forward. We do not plan to discontinue this for the FDP

institutions that are currently participating with us. We will plan to continue, and we await to hear from the FDP what they would like to do.

NANCY WRAY: Thank you. I think we will assign this to the Research Administration and take it up. I think it sounds like a very worthwhile project. Thank you.

BOB MACDONALD: Okay. I give you Jason.

JASON HITCHCOCK: Good morning. I'm Jason Hitchcock, eGovernment Program Leader at USDA, CSREES. I just thought I'd give you a real quick update on where we are with Grants.gov implementation. We've been doing a lot of various pilots, as well as real actual implementations with some real programs, so there's been a little bit of confusion out there about what's what and what's available to whom. So hopefully I can clear that up for you.

We're obviously through most all of our testing of Grants.gov with our forms and instructions and our requests for applications. We have one competitive program out there that's open right now that's available for applicants to submit electronically through Grants.gov. That's the Biotechnology Risk Program. That closes on February 16th this year. And we're encouraging folks to submit electronically for that, through Grants.gov. There is also a paper option. Paper applicants to this program will be submitting on the new forms as well, the new R&R forms and agency-specific forms.

We're also moving forward with non-competitive programs. And some of you institutions may be receiving word that you have the option to submit electronically for some of our special research grant line items, if you're a recipient of those. They're selected line items that we are going to be allowing electronic submission through Grants.gov.

The part of the testing that's gotten a little confusing, as we are also working with five institutions to submit electronically. These are the five institutions we've been working with to submit for right now. Children's Youth Family At-Risk Program, which has already closed. We did receive one application through Grants.gov from Cornell. The NRI, National Research Initiative Program, is also available for electronic submission for these five institutions. We're trying to, you know, build up our depth and breadth, build some confidence within the agencies as well as out there in the regions.

So these programs are available for these five institutions to submit through Grants.gov. The Integrated Organic Program has already closed. We did not receive any. And the Integrated Food Safety will be closing shortly I believe. Hopefully we receive some electronic applications for that. We may be offering other opportunities for these five institutions as well, but we've been getting a lot of questions, you know, hey, I hear NRI is available. Well, NRI is only available right now electronically, for these five institutions, because only these five institutions have the actual specific instructions on how to apply electronically through Grants.gov for that opportunity.

And I mentioned our forms are transitioning. Right now current hard copy applications are, unless otherwise instructed, applicants are supposed to be using our current paper forms. For the Biotech Risk Program, for the special research grant line items I mentioned, if you're a recipient of those, those will be expected to come in on the new R&R forms.

We are transitioning away from our old kit so that for all next year's programs the old forms go away. We'll be using all new R&R forms, as well as the CSREES agency-specific forms, as well as providing the option in the coming year for electronic submission through Grants.gov for all programs. That's all I have.

NANCY WRAY: Are there any questions?

JASON HITCHCOCK: Questions for me or Bob?

NANCY WRAY: Thank you. Department of Energy, Jackie.

JACKIE KNISKERN: Good morning. My name is Jackie Kniskern. I'm with the Department of Energy, and I've just got a couple things to tell you about this morning. Just some basic simple updates. You've probably been seeing all along here, we're putting everything on find, and this year we hope to have 75 percent or more of our discretionary programs, most of our research programs on apply and, of course, we take everything electronically. So that's really not much of a change other than almost everything will be through apply this year.

Something that's kind of a plug for our 10:45 session this morning is we're doing our subcontract reporting through the new eSRS system, and this is just some basic information that you'll be able to get later when it gets posted up on the website. To tell you what we're doing with this, Tammy has been really heavily involved in this. This is going to take the place of those standard forms 294 and 295. You're going to do all your subcontract reporting electronically through this system. And Marv Grissom from the Department of Energy will be here at 10:45 to talk about that system.

One of the things that's been going on at Energy that's been taking up a lot of time for everyone is implementation of the Energy Policy Act of 2005 that was put into law in August. I've got three areas here I'd like to highlight that you may have some interest in.

The first one is other transactions authority. This gives DOE the same type of authority that DOD already has. We're implementing this only as a financial assistance area, similar to a cooperative agreement. Our interim final rule is out there, but the way the law was passed, we can't use this authority until after we go final, so that won't be until sometime in the second half of fiscal year 2006.

One of the interesting things here is that you do have to have a for-profit company as part of a partnership, but it will give DOE another tool in making some research awards in areas where maybe traditionally people have shied away from trying to get involved with the government for funding that area of research. And Trudy Wood has the lead on that.

Another area is cost-sharing. DOE has always had a lot of cost-sharing requirements. What the EP Act of 1992 did was combine all of those into one area. And we're pretty much required now to get cost-sharing for all research and development. If it's just basic or fundamental, and we'll probably be excluded, any of you that deal with the Office of Science on a regular basis, they won't have the cost-sharing for the types of things that they do.

The rest of it's 20 percent for research and development, a 50 percent cost-share for demonstration or commercial application activities. That's pretty much what DOE has been doing since EP Act of 1992. There's also the ability of the Department to get rid of that if that's not a good idea for that particular activity that's being funded.

Another thing is impartial review of the merit. I'm not quite certain why that made the law. That's pretty much what we do now anyway, even for our non-competitive activities. Something that's a little interesting is that we were authorized to open up a lot more of our activities to allow the labs and universities to compete.

And that this means for the universities is there may be more funding opportunity announcements out there, as we can now go out and say, hey, do you have something that could help with the labs, compete against the labs. So there may be some additional opportunities coming out of this for the universities. It also promotes consortiums and partnerships to a greater extent than what the departments had before. And there's just some contact info, and that's it.

NANCY WRAY: Thank you. Are there any questions? Yes.

PARTICIPANT: I'm just curious, the other transactions . . .

JACKIE KNISKERN: There's differences in some of the patent requirements, for one thing. And there's another area, which off the top of my head I'm now forgetting.

PARTICIPANT: . . .

JACKIE KNISKERN: I mean, that's one of the things. And the idea is to get more for-profits involved where they would not necessarily want to become part of a partnership because of some of the restrictions that you might have in your standard terms and conditions and those types of areas. So we're hoping that this will bring some more people in once we can get it so that people can use it. They've been trying to give this authority to DOE for years. It just finally got passed, so we'll have to see how it works. And our programs model considerably off of what DOD has. Anything else? Thank you.

NANCY WRAY: Millie, EPA? Millie Lee?

PARTICIPANT: Let me just say that Millie had a conflict and EPA doesn't have anything egregious or fabulous to report, so I'll just sit down.

NANCY WRAY: Thank you. NASA.

PAUL BRUNDAGE: Good morning all. I'm Paul Brundage with the National Aeronautics and Space Administration. I learned earlier this week that I'd be speaking today. Contrary to your agenda, Monique Sullivan will not be speaking. She's moving to Mississippi to the Stennis Space Center to do some work there.

So that said, I'd like to speak for a minute about our success with interfacing with Grants.gov. We expect to post at least 75 percent of our solicitations on Grants.gov

applied during fiscal '06. The forms and submission instructions are on the website listed there. So far, well, as of the 10th, we've had 19 applications that have been submitted via Grants.gov.

The NASA-specific PureEdge forms are undergoing what I'll call final testing. We had to develop interim forms in rich text format in order to manually ingest the data into our system. In any event, the PureEdge forms have been tested. That's done. They've been approved. That's moving along well.

This manual ingest of the applications submitted via apply, we're working on the completion of that and it's dependent upon these PureEdge forms and the new senior key person form-in-form. And I learned I think just this morning from one of our engineers, Greg Lindsay, that that is now done. It was completed yesterday or expects to be done today. But that's all set.

This manual ingesting of forms, we've been doing this since September of last year and expect to do it into February. We currently have 15 programs posted on apply. The PureEdge form requirements relate to this R&R senior key person, and we're targeting, well, now it's been finalized, so that's all set, completed, two back in August and one in December. So that's okay. The development of this automated application ingest, we've been working on that for some time. We're expected to complete that in .

[Tape change]

PAUL BRUNDAGE: . . . the post-application packages using NASA-specific forms will be February '06. Automated ingest, February '06. And of our programs that are out there, the first proposal due date will not be until April 14, 2006. In short, NASA is on schedule to meet OMB's suggestions for interfacing with Grants.gov.

Let me just spend 90 seconds and mention another matter. I spoke briefly with Janice Goddard this morning concerning receiving payments from the National Aeronautics and Space Administration. And she said people are telling her that there are difficulties, that they're going to do this, new letters of credit are going to have to be instituted, and on and on and on. And in general, a long tale of woe was given to me.

I sympathize with Janice, and I know many others are having the same difficulties. I submit to you that it's not you. The universities, you're doing fine, you're doing well. You've got the program. We've got the money. You're going to be paid. All of that is well. Also, it's not us. Yes, we've got the money. You've got the program. You're going to be paid. And we know that's going to happen soon.

The difficulty is in this software which we're trying to use to consolidate the financial records for all of NASA centers, Goddard Space Flight Center, Kennedy Space Center, etc., and it's causing us some problems. We hope to have that solved in the not-too-distant future, but in the meantime, we simply ask for your patience. And when people tell you at NASA that we don't know where your money is but we're going to find it and get it to you, we ask that you simply understand. It's not you. It's not us. It's the software. Are there any questions? It was a subcontractor. I'm being somewhat facetious.

NANCY WRAY: Thank you. Joe, NIH update.

JOE ELLIS: I'm Joe Ellis with the NIH and I have the pleasure to give the NIH update today. First we're going to start off with the good news. NIH does have an appropriation for 2006. Now the bad news. NIH has an appropriation for 2006. Unfortunately this year's budget has a very tight structure to it. We were expecting very modest increases.

And as you've read in the press, there's been a rescission to discretionary funding. They cut our budget by \$286 million. As a result of this, we're applying what are very tight financial policies that we haven't seen for a very long time at NIH. And we're really moving away from the financial management plan that was in effect from the early '90s until really last year. So NIH, you got a foretaste of that under the continuing resolution where we reduced the amount of funding we're providing to non-competing awards to 80 percent of the committed level.

Now in the final budget, after adjusting for this rescission and other factors, in order to be sure that we have money available to pay competing applications, we're applying reductions to non-competing commitments this year and funding those at 97.65 percent of the amount we have previously indicated or committed. The future year commitments to those non-competing awards are going to be reduced by the same factor, so we're already applying reductions to those commitments for 2007 and beyond.

Competing awards are also seeing a reduction, though it won't be as obvious to individual awards. When we prepare allocations for funding, you allocate a number of awards and a number of dollars to do that. This year, the average cost of those research project grants is going to be held to the same level as we used in 2005. There won't be an increase. That doesn't mean that every award will go out at the same dollar amount or that applications as they come in need to be held to a certain dollar level, just that when we allocate dollars and the number of awards, that will be held at the same level.

What that means is that those allocations and the amount available for competing awards will not include what we used to call BRDPI, actually the biomedical research and development price indicator, so the average cost of those isn't increasing by that factor this year, so they are not going up by that 3 percent and maybe a little bit of change. That means that they're at your commitments because the base years reduced are also similarly reduced. But for this year we will continue to provide a 3 percent escalation factor for the non-modular budgets that go forward.

Other grant mechanisms are also going to be seeing similar restrictions on the overall budget allocations, that because of the variances in individual ICs, each institute and center will be posting a funding policy for FY '06, which is going to be consolidated into one NIH web page that'll give you one stop to go to to look at HIC's policies. But those are all going to see similar reductions.

Of course, we're expecting that the success rate is going to be constrained again next year and these are just a sign of tight budget times that we're going to have to work through over the next few years. Moving on to NRSA, when we announced the funding policies for FY '06 this Monday, we also published the guidelines for fellowships and training awards and made some modest increases to those. Specifically we gave a 4 percent increase to the stipend level for post-doctoral trainees and fellows with . . .

levels of experience and one year's experience. And we give the new amounts up on the slide.

For institutional allowances, for individual post-docs, we've increased that by \$500 really to recognize the increased healthcare costs. That's published in the reference guide notice that's been provided. Our salary cap continues to be legislatively mandated. Executive level one, that's not been changed for quite awhile now. The level last year was \$180,000. It's been increased for FY '06 to \$183,000. We're going to publish a notice on that in the next few days. We're also going to publish a notice on the legislative mandates that are in our appropriation. There's really no change there, but that notice will be released fairly shortly.

Now to some other topics, just to hit these very lightly. On the multiple PI question, our request for information, we've been working with the analysis of that for a while now and have a large committee at NIH who's really wrestling with this topic and which is really a very major change in our approach to applications. There's, you can imagine, there's quite a bit of discussion.

We will be coming out to the community at some point to focus group to get some information and feedback on how best to handle splitting projects when you might apportion for multiple PIs, when that's useful for scientific purposes, when it is not useful for sponsoring team science. We do plan to pilot this probably for at least a round or two with requests for applications beginning in May.

The Center for Scientific Review, specifically their new director, Dr. Scarpa, announced a pilot program to try to shorten the cycle for review, especially for revisions. They selected a group of study sections, I think around 40, and those study sections will try to get the summary statements out quicker to particularly new investigators. And if there aren't major revisions required, allow them to come in very quickly in the next review round to try to accelerate the time for re-review and hopefully award.

E-submissions, thankfully I'm not going to be able to give you the full feedback on our status with those and plans, but there are two sessions to recommend you to that will review NIH's experience with this and our plans. The first is going to be this morning. Marcia Hahn, who gave an outstanding performance yesterday, explaining the 424 R&R. I've gotten numerous compliments this morning. And I know those that saw that session were very pleased, at least with her performance, if not with all the information we gave.

In any case, she will be discussing an update on our implementation of the 424 this morning at 9:45 at the Administrative Process Standing Committee meeting. And tomorrow at 9:00 a.m., Megan Columbus, who is really on point for this process for NIH, will be discussing our experience on the first round of applications for SBIRs and STTRs and next steps. So this will be a good opportunity to bring yourselves up to date on these processes.

I'd like to take questions, but I think we're running out of time. No. If you have questions, now is a good time to ask them. Well, that couldn't have been that good. Okay. Thank you very much.

PARTICIPANT: I have a question. Any advice we should be giving to younger investigators and people applying to . . .

JOE ELLIS: For the new investigators?

PARTICIPANT: Yeah, first-time folks.

JOE ELLIS: Well, part of this, you heard, is the pilot is focused primarily on new investigators and that might be expanded to a broader group of investigators down the road. There's also an active committee at the NIH that's looking for tools to help the transition of investigators from a trainee career development mode to an independent investigator. It's a discouraging time because funds are tight, but one of the things that we are doing by applying these cuts is to make sure we have sufficient opportunities for competing applications and new investigators. So I try not to discourage them too much.

PARTICIPANT: Hi, Joe. On the announcement that came out on Monday, there was a statement that says the amounts provided for competing RPGs will be managed to an average award amount equal to FY 2005. Some of our investigators are interpreting that as that they can't ask for increases in their competing renewals. Could you clarify or expand the language here and how does that relate to that question?

JOE ELLIS: Okay. Well, the policy itself that was published on Monday is our funding policy for FY '06. It does not constrain or indicate a limitation on what can be requested in applications. Some institutes and centers have policies on how much can be requested on competing renewals, but there is no NIH policy limiting same.

So I would not dissuade people from asking the dollars that they need, just to realize that when we do apply our reductions to awards, programmatic cuts, if you would, it's more than likely that those will be more constrained than in previous years, but probably you would not notice that if you looked at one award by itself. We're going to try to post some questions and answers that may come up as a result of this policy on the NIH web page, and that would be one that I will take back and we'll put Q&A up on that. Any other questions? Thank you very much.

NANCY WRAY: Thank you. Joanna.

JOANNA ROM: I am told we're in full compliance with Grants.gov, and if you have questions about Grants.gov, there are people here I can refer you to. What's new at NSF? In a conversation this morning, I was talking to somebody about Jerry leaving, and we had a whole long conversation, realized somebody was talking about Jerry Stuck.

I was talking about Jerry Glaser, who was our division director at Grants and Agreements, retired January 3rd. And I'm happy to announce that Mary Stantonastasso will be the interim head of the division of Grants and Agreements. And that's going to work well, I think, for all of us because being the existing head of the Division of Institution Awards Support and working with the grants folks, I think we can really strengthen how we do things. We think we do them well. We think we can always do them better. So I'm very excited about Mary being interim in that role.

I have three quick things to discuss with you. In December we sent out an announcement about NSF's strategic plan process that Craig Robinson, who some of you know, is coordinating for the agency. And this is a process we're required to do by law, the GIFRA requires it. But it's also a very important communications and planning tool for the agency, factors into our budget, factors into our performance activities, and is a chance for a national dialogue about what NSF does.

So we have the previous strategic plan out on the website. We put a request out to the community, which we then conveyed to FDP and sent out. And it's on our website. The link is easy to find. There's another few, I think the deadline is the 20th, although if you sent something the 21st, it's a weekend, so I don't think people would mind. We really do want community input. And there are two broad questions, and you don't have to remember this. This is all on the website.

But I would particularly call your attention to the second question, what broad characteristics of near- and long-term environment for S&E research and education should NSF consider and address in its next strategic plan. And if you have thoughts about this or have colleagues who have thoughts about this, I really encourage you, again, online there's a little, you know, send in something mechanism. It can be anonymous, although we're interested in hearing who it is if you're willing to identify yourselves. And to take a look at that, because it really does have some implications for the future as coming from the agency that supports basic research in this country.

And then this is just a note about the timeline. Basically it's a very open process. We really want to look back at the old plan. We want your input for, as we develop the new plan. It's going through an iterative draft process. The plan, the draft plan, the revised plan, future plan will be available for public comment later in the year, will be discussed with the community, the National Science Board, and it doesn't have to go to Congress or OMB until, you know, the final version until September of this year.

Another thing I wanted to mention, changing topics entirely. I don't know if Tom Weber is in the room. Hi there, Tom. But one of the things that we've finally got the conversation going, we've engaged the borg, I guess is one way of putting it, is to talk about our no-budget proposal pilot and whether this is something that we can build on the lessons learned at NIH with the modular grants. NSF has smaller awards. NSF reviews the awards somewhat differently.

So we're not sure we could adapt the NIH model per se. But we do think there's a big opportunity for resource savings by not requiring full-blown budgets until we're close to making an award decision. And given our success rates of 20, 30 percent success rates, that means a lot of effort can be saved by only having awardees prepare full-blown budgets. So we're talking in terms of, and again, this is very preliminary. We have some volunteer divisions.

Tom has been pounding the troops to get some commitments, which actually wasn't very hard to do. I think he got some divisions who really stepped up to the plate and saw the benefits of this. We need to talk in terms of our internal senior management. What we would be looking at would be some special way to involve FDP.

So if we do it on a division basis, it would be all proposals or all proposals in a given division or given program. It would be FDP and non-FDP institutions. We would look for a special way for FDP to be involved in the feedback, maybe having FDP institutions specifically commit to not doing internal budgets for the duration of the pilot.

Those are things I think we could probably discuss in the basic assistance discussion this afternoon. But I just wanted to let you know that that was happening.

And then one other update item I wanted to, oh, there it is, is we are continuing our activity of providing, we have our, I think most of you are familiar with our NSF regional seminars. And we have also added some special focus seminars. One we did last year. I believe it was tribal colleges. This year we're doing a specific one that emphasizes and provides support to HBCUs, and that's going to be taking place in March in Atlanta. We also have our Boulder one coming up this spring, and we're going to be at the University of Maryland this fall. So that's all she wrote. And I can't make it go away. Do you have any questions?

NANCY WRAY: Thank you. And our final update, Lambert, are you here for ONR. Oh, Debbie.

DEBBIE RAFI: Okay. I just have a few things. I have to confess that I am just the messenger. I found out recently I was going to be doing this. Senior leadership, our Admiral Cohen has finished his term at ONR. I think a three-year tour has turned into, I don't know, five or six years. But the change of command is scheduled for January 20th, and his successor will be a person referred to as Admiral Bill Landay. I do not know that much about him, but his bio is on the navy.mil website if you'd like to look him up. It's spelled L-a-n-d-a-y. So it's Admiral Landay. So that will be happening in the near future.

The second area has to do with our internal information systems. And the only impact that you may see from our changeover, actually we're right in the middle of crossing over from one system to the other, is that the grants have to be put on hold at ONR because the systems actually generate the grant document apparently. It's pretty automated, from what I'm told.

So you may have noticed that grants are not being issued right now out of ONR. The goal is to restart that process the 1st of February. That is our goal. As you know with system transitions, there's always glitches. But contracts or procurement instruments will continue to be generated out of ONR because we do those offline.

Then the final area, I think it's called electronic proposals. I think that has to do with this Grants.gov thing that's out there. You know, I'd much rather talk about . . . reporting or audit resolution or payroll certification, excuse me. I have some cheat sheets here and I'm going to read a script. I don't know what these acronyms mean, but I hope you do.

We, of course, we at ONR are committed to electronic submissions. I think we are starting discussions with MIT to do a test. I've been told something like a system-to-system interface with MIT is going to be our first test of this eGov or this electronic proposal thing. That is targeted to start and get through the spring of '06, so I think discussions have already started and hopefully we'll have some progress to report in the May meeting.

The other commitments we've made is for government fiscal year '06, which we're in the middle of, they have committed to getting a goal of 75 percent of our BAAs having the electronic submission requirement incorporated. And then in government

fiscal year '07, the goal is, of course, 100 percent of our BAAs will have this requirement for e-submission.

There also is one final note about this SF 424 R&R, which Marcia seems to be the expert on, so I'm sure she could enlighten me on what that means. But the note here says that ONR does plan on using that, the system-to-system interface with this SF 424. I don't know. I'm probably really doing a disservice trying to brief you on something like this. But, you know, afterwards I'll take questions. There are people back at ONR that can answer these questions much more intelligently than me. So hopefully there's no questions on it. But I'll be happy to answer questions about A21, A133.

PARTICIPANT: I have a statement.

DEBBIE RAFI: Statements, I can handle statement.

PARTICIPANT: That the SF 424 is the only form that ONR is going to use, and all their data elements and requirements fit in that and they don't really . . .

DEBBIE RAFI: Did everybody hear that? Good. You're not going to ask me a question . . .

PARTICIPANT: It's not really a question for you, Debbie, but I do, I did want to ask sort of a general question for all the agencies that are implementing Grants.gov. Is there any thought about providing what I call a safety valve for those applications that may fail for inconsequential reasons? In other words, you know, something happens bad but it's really an okay applications, can you do it by paper essentially?

DEBBIE RAFI: I will definitely take that question back to our lead person at ONR. I leave it open to the other agencies to comment.

PARTICIPANT: Within EPA, or at least the research and development part of EPA, we're changing our electronic proposal instructions to say, if I recall correctly, if you have a problem during the Grants.gov transfer and you can show to us within a relatively short period of time that you contacted Grants.gov and you have an account number or a record of the contact of trying to solve the problem of the transfer, then we will be able to take the application a little later than we would have otherwise.

Now we're not talking days. We're talking an hour or two. Yeah, I realize, but we have a contact point ourselves, but we are encouraging people, we're giving some instructions that we think will help people who have not done the electronic transmission often. And, again, we have a contact point in there for Grants.gov.

We have their number, that you've tried to solve it with them, you've tried our tips, and we have our own contact point that you can discuss this with immediately after you've had the problem. So we're trying to work that. And for our part, if you all have any suggestions on a better way to take care of these transmission problems, we're open to them.

JOE KONSTAN: Great. Thank you. Some of you may have figured out that you've gotten an extra 20 minutes of federal discussion and over what we budgeted. We had a quick discussion and we decided that we would not charge you for that extra information. We like the concept of no-cost extensions. We will therefore have the no-cost extension of this session as needed to complete the content and juggle things afterwards at no additional cost to most of our participants. Some of you, we can't say.

When I was elected into the position as faculty representative, the first piece of advice I believe I received was you will be successful if Bob Decker is happy, which sounded not bad, you know, a couple of drinks, a nice dinner. And then I discover that Bob Decker will only be happy if the Faculty Burden Survey is completed during the time that you were in this position.

And while he will be the first, I'm sure, to say that he is never going to say things are completed until the final report is delivered, I am thrilled to be able to bring him and a team of people I will introduce up to provide preliminary results that suggest that at least the data collection and its initial assembly into a pool of data has been successfully completed.

And so I'd like to bring up Bob Decker, who is a faculty representative from Northwestern University, as well as Scott Crawford from Survey Sciences Group, and Leslie Wimsatt from the University of Michigan to share with us what they have learned in this initial stage. Welcome.

BOB DECKER: I'm overwhelmingly humbled by my introduction and I don't know what else to say except to blame this whole catastrophe on Marv Paule, who, needless to say, isn't here. For those of you who don't remember Marv, he is our, was the past chair of the Faculty Steering Committee.

And when the Faculty joined the Federal Demonstration Partnership, I think the partnership really became a real partnership since, by and large, the Faculty are the clients of the federal agencies and of the universities. And we're actually the people who do the work. You spend all your time trying to help us, and without your help we couldn't get it done. But I think it's important that one realizes that the faculty ought to have some input into the kinds of issues that we feel are important in us effectively and efficiently conducting our research activities.

And so when Marv joined the FDP I think at the beginning Phase 3, he stood up in the back of the room and said I've had it, I have so many problems dealing with the management of my federal grants that I think we need to have some information about how this kind of activity is affecting faculty. And that was the nius, the beginning of the notion that maybe we ought to know what the faculty feels about how our federal grants are administered, how they function, and what the impact of the administration and function has on the ability of the faculty to actively conduct their research.

And so after a number of fits and starts, we got the survey process going a couple of years ago. And the faculty sat down at the FDP meetings and they talked about what they thought were the beneficial aspects of the way the federal government managed their grants and the problems that faculty felt that they were incurring in an increasing degree over the years of running their grants.

And it was quite clear that every faculty member had a different perspective about, you know, what it took to effectively manage a federal research grant. And we

started talking about these issues, and it was quite clear we needed to get somebody from the outside to help us basically crystallize our thoughts. And at that point in time, it fell upon my shoulders to continue this process. And much to my dismay, I agreed to do this.

And as Joe just said, I think we actually are going to come to complete this project and I think the information you will receive today will be tantalizing and I think the final report will be very valuable to the FDP. It will give you a clear indication of what the faculty feel about how their activities affect their daily lives and how efficient they are in spending the federal government's money in conducting research.

The first thing was we needed help, and that help came from Leslie Wimsatt, who is the director of curriculum development in the Department of Family Medicine at the University of Michigan. And we chose Leslie to help us because she spends a good deal of her time looking at how faculty workloads affect the efficiency of faculty. And we felt that this was just the kind of background we needed to get the process going.

And she became involved, and in 2004 spent some time with us at the FDP meeting, basically talking about what it would take to put a survey together. And the faculty agreed that this would be a good addition to our subcommittee on the survey. And so Leslie and I have gotten to be very good friends and have worked hard over the last year and a half to put the survey together. Once we got the survey together, we had to figure out how to administer it.

And at that point we had all decided that a web-based survey seemed to be the best way to get the faculty at FDP organizations to respond to the survey. And at that point we sent out submissions to several survey companies and ultimately chose Scott Crawford's company, Survey Sciences Group. And Scott has had significant interactions with the NSF and a number of our other federal agencies and he's, turned out to be ideally suited to conduct our survey.

And the survey was begun this fall, after considerable amounts of work. And we have collected the data, and we are now in the process of analyzing that data. And today Leslie and Scott are going to give you a preliminary result of what the faculty feel are both good and bad points about how their federal government helps them conduct their active research. And so I'm going to start, I think, with Scott. And both Scott and Leslie and I will spend the next 20 to 30 minutes giving you some preliminary input upon the data we've got.

SCOTT CRAWFORD: All right. I'm going to, the way we're going to structure this, I'm going to talk a little bit about the survey, the administration process, a little bit about the, how we actually conducted the data collection, some of the results with, you know, how many responded and what our success rate was there. We'll move over then to, Leslie will talk a little bit more about the actual substance of what some of the key findings were from the initial look that we've taken at the data.

Bob gave a really good background so I won't spend any more time on that at this point. At the questionnaire stage we, just to give everybody an idea of what was in this questionnaire. Let me ask first, are there any respondents in this audience? We have a few. I won't ask any non-respondents. That's probably not the right question. There's probably a few of those too.

We did go into a section of the demographics about the faculty that were responding, who was it that we were actually speaking with. We were asked for a simple random sample, so what does that really mean when it talks about federally funded faculty. Research involvement, what level they are, PI, co-PI, what size grants they have, how much work they actually do with research, and then some descriptive information about their federal grant funding, the burdens that they have in conducting that research, the support that they receive, and ultimately their overall climate that they perceive as well with regards to federally funded research.

I was brought on board into this effort a little bit, almost immediately after the pilot, initial work that was done, so actually I'm going to have Leslie address this one slide and then I'll continue on. But we did do a pilot study to test the questionnaire a little bit.

LESLIE WIMSATT: We thought it might be useful just to remember that in the spring of 2004 we used 14 institutions, 14 member institutions of the FDP in the pilot project. Thirteen of the 14 ended up participating at that time. That involved about 113 faculty in the target sample, of which about 72 responded. And that's useful as you reflect through some of the information later on because there's some really strong similarities between the pilot and some of the outcome data which are assuring.

The post-pilot revisions simply involved revisiting some of the questions, speaking with the committee and faculty who responded to it, and toning it up a bit. I mean, what's the purpose of a pilot anyway if not for that. So some to make sure that the sample was going to be more pure, and others just getting the burden-related questions cleaner.

SCOTT CRAWFORD: So this was wonderful actually. When we started work with this after we had a piloted questionnaire, it made my job a lot easier than it typically is. But there was one difficult task that we had to conduct that really actually took the majority of the time in administrating the survey. I think we were initially talking, we were hoping to get this fielded sometime in the early spring of last year. We did get the effort started in the early spring last year, but it took pretty much throughout the summer, into the early fall before we were able to field, as we got the, went through the process of collecting all the lists of faculty from the institutions.

So we initially invited 99 FDP institutions. Faculty and admin reps were instrumental in this effort to obtain the lists. We also went through a process of getting IRB approval from any institution that was requiring that. That was also quite an effort, as I'm sure you can imagine. And in the end, we had 69 institutions that were able to provide the list, obtain their IRB approval, and agree to participate in the study. From that we obtained over 30,000 faculty respondents, from which we took then a sample, a simple random sample of 23,325. The sampling was done, we wanted to keep it as large as possible while keeping the budget in check, and so that was really the purpose of the sampling.

We did go with the web-based survey approach, as Bob described. This was, the questionnaire was programmed into a fully interactive web survey where, for the most part, between one and five but sometimes up to six or seven questions were

presented on a screen at a time with a submit button in between each page. This allowed for responses to be saved while the process of the survey was going on.

We did hear some criticism or some thoughts about a survey like this among a population like this who is already burdened, are we going to have a lot of break-off after the first two or three questions. And so we wanted to make sure that if we did get break-off we were capturing those responses, at least the half of a response or whatever we did get during the first part of the survey. We do an extensive testing process for any web-based survey. Part of this is the actual instrument itself is testing.

A lot of this is also any question type or any kind of format that we use in the survey we have tested thoroughly. Compatibility is always an issue with web-based surveys. There are lots of different browsers out there, and what looks good in one browser doesn't necessarily look good in another. So we spent some time ensuring that we are coming out with an instrument that is, you know, functional, useable, that works well with all different browser types, all different operating systems. You know, it can never be 100 percent, but I think we did a pretty good job getting to a questionnaire that worked well.

And then the content and comprehension testing, we sent the survey out, prior to fielding in the web-based format, to, I think it was the Faculty subcommittee working with Bob on this questionnaire. So we had a lot of input at that point, once the questions actually got to screen, once we actually see them in the web survey, what does it look like.

The data collection finally took place in October. We mailed out a letter to each individual respondent. This actually happened at the FDP office here, and I think Jerry Stuck himself was licking envelopes. But that process took about a week or so. It happened during the week of the 10th of October, an e-mail invitation then followed up the following week, and we had about four reminders paced at about three to five days apart, where it would go to any non-respondent at that point, so we asked them to participate.

Response rates ranged considerably by school. It was really interesting. Everything from, there was an individual school with no respondents, but up to 57 percent. The average was about what we've seen in other national studies like this, around 40 percent. The numbers are being worked out right now as we kind of begin to understand truly what our proportion of the sample was eligible to participate.

We're looking at the responses they provided to make sure that we were capturing the federally funded, full-time faculty researchers. And we did see that there were a few schools, probably more than a few, that provided us with just simply whatever they could, which meant a list of employees. So we had, there's a little bit of process of cleaning up that's going on.

But the nice thing that we saw is that there was a completion rate of nearly 90 percent, which for a web-based survey that took, you know, in the 15- to 20-minute timeframe, is actually very good. You usually see in that 90 percent range. If it gets up into more than 15 or 20 percent breaking off, then you have a little bit of worry. But from my experience with other web-based surveys, this 87.1 percent was right on par. At this point, I'll turn it over to Leslie to talk a little bit about the results that we saw.

LESLIE WIMSATT: Thanks, Scott. We thought it would be really useful if we could provide you with a profile of the respondents, you know, who is the FDP, as it were. And you can see the breakout in terms of our response group. About 65 percent, actually 64.9 percent of the faculty were tenured. Nationally, through the U.S. Department of Education, having more instructional faculty in the mix, the national average is around 54 percent. This group is much more skewed to having a research focus, so it's slightly different.

This is quite like the piloting of the survey, very similar. The pilot was a little higher, 76 percent tenured. On the tenure track, 20.7 percent, and either not on the tenure track or they don't have a tenure track system of any sort is around 14.3 percent of the group if you aggregate that data. If anything, there are fewer people in the no-tenure track or not on the tenure track than you see nationally, and nationally there are a lot of people in that group, if you're familiar with faculty work life issues currently.

We asked the survey participants, during the 2004 academic year what was your principal activity, and this is what they had to say. So our group has a heavy, heavy research involvement. We asked them to give us their academic rank. At the time of the survey taking, 51.4 percent were full professors, 21.1 percent were associate, and 22.7 percent were assistant. Nationally this skewing toward full professorship is currently the norm. There's a very large group of senior faculty members operating nationally across institutional types.

We asked them what their principal field of research happened to be, and this is what they had to say. And as you can see, it generally broke out into ten fields of research with sort of an aggregated other category. And it ranges from 2 percent of the faculty respondents in education up to 32 percent from the biological and life sciences. And my understanding from Bob is in many ways this is very reflective of the composition of who's involved with your organization and what their roles are in the research community.

Then later in the survey we asked them to please provide the total number of federal, and we also asked them about non-federal, research grants received during the '04-'05 academic year. We asked them about it when they were a PI, also their activity when they were a co-PI. And this is what they had to tell us about that.

Given the fact that the data has, is in the very early stages of analysis, I can assure you that the responses vary significantly by whether the people had a research emphasis or instructional duty emphasis. I can assure you of that. I can assure you that it varies by tenured and non-tenured faculty. And it most certainly varies by field of study, because the way those documents, those grants function is just so different across fields. One point three was more the average in the math area, for example, whereas 2.1 or 2.0 in physical sciences, engineering.

We then asked them a similar question, kind of getting to the direct cost issues, and this is how it broke out by academic rank. Again, these responses are going to vary when we get farther into the data analysis, but just to give you some range perspective, there's about a \$200,000 difference between research and instructional faculty, standard deviations floating in there. Tenured versus non-tenured, about a \$200,000 range difference. And math versus physical sciences, a \$300,000 difference in terms of what type of funding.

Then we asked them conceptually, and if any of you have ever taken the National Survey of Post-Secondary Faculty, known as NSOPF, which is distributed nationally to the majority of higher ed institutions in the United States, this is sort of a work effort type question where they're asked to break out how they're spending their time in a typical week or a typical year.

And so you can see that our respondent group is quite active and busy with research projects. Our pilot group was the same way, very strong parallels between the percentages reported in each of these categories. And, oh, I wanted to point out, just we rounded some of this data to get it up for you today, and so you're going to have a couple totals that we tried to make a note on whether, it doesn't come out to 100 percent so don't point that out after the presentation.

Of the total time you spent on work related to federally funded research activities this past academic year, what percentage of time did you devote to each of the following. And this is what they had to say. Well, they devoted most of their time to research, active research, reviewing literature, designing studies, running experiments, collecting and analyzing data, writing up findings, publishing and presenting the research. That's their active time.

They spent around 23 percent on pre-award tasks, submitting their proposals and budgets, writing same, applying for approvals, developing protocols, drafting those safety and security plans that are often needed. And on post-award tasks, down to about 20 percent, which drops into things like purchasing supplies and equipment, supervising budgets, managing the personnel that they brought on board for a particular project or program, complying with regulations, monitoring safety and security plans, writing reports, etc., etc., etc.

The time spent on research does not statistically vary by rank when viewed in the aggregate. And I thought you might find that interesting. How much do each of the following tasks related to federal grant management take time away from your active research, what's pulling you off the bench, and these are some of the David Letterman's top . . .

[Tape change]

LESLIE WIMSATT: . . . it would be absolutely insane to try and address it with you today. It varies by how large your administrative role is or not, whether you have support because of that role or not. It varies by academic rank considerably. But we do know that these tasks and others, and there are a slew of other tasks we put into the survey, of this particular group, for example, at least 76 percent of the people are losing bench time because of the first item up there.

That's in the aggregate, granted. We know that 50 percent on the second item, 50 percent on the third, 65 percent on the fourth. So this is just a lot of people having trouble with these tasks. And we're basically have them sort of rank ordered in a preliminary analysis, but this dis-aggregation is going to be essential to really come up with useful information. We all get lots of information. Trying to keep it useful is always the challenge.

How much additional time do you, could you devote to active research if you had more assistance with administrative tasks that are linked to federal grant management.

And these were some of the thoughts of the faculty who responded in terms of how they could see that support helping them. Of the group that said less than two hours a week, about 5 percent of that group said none, forget it, it just wouldn't give me any more time at all. But everyone else felt that there was a possible help there.

And what's useful sometimes, and just looking at these figures, isn't maybe so much from a research statistical analysis point of view as a decision-making point of view, you know, how many people does a certain task or support group impact. And when you kind of look at how the percentages break out, I think that can help guide the thinking of the FDP and their decision-making about, well, then what do we do, who's impacted, how many people are impacted.

We probed farther and said if you could reallocate direct costs to administrative support, what percent of your federal grants would you like to assign for this purpose. And to kind of put it into just a nutshell, 77 percent would like to assign at least some direct costs for administrative purposes. And then to maybe understand the faculty in a different way who are providing this information and engaging in this survey and being, looking at research from, through their frame of reference, we asked them questions about their perceptions and their beliefs and, you know, who are they, what do they think.

Despite the burdens, despite how many are responding to these different questions, that they need help or they're swamped or it varies by their rank, 92 percent would still do it all over again, they love research. That's the takeaway. They choose the career. They're working in an environment that tends to reward research overall, which you can see here. They think the burden is going up in recent years. Seventy-six percent say, which again just is so interesting with the previous table, 76 percent say that the direct cost dollar reallocation could free them up to be more active researchers.

Speak a little about the support in-house, whether they can reassign certain duties. That may have more currency in your thinking when we dis-aggregate the instructional versus the research faculty, and how is that work life different for those two groups. And if they love research equally, how do you empower people to be able to do what they love with the type of role they have at their institution.

The second item here may be of concern. This is a perception obviously. It would be a concern if I were teaching and trying to bring a group of researchers up to drive research nationally to see that 62 percent are feeling that generally in their labs their people are not coming through the old way or they're not planning to.

And really not that many are not willing to submit federal grant proposals in the past. And there are just many, many ways to dialogue about that issue. It drives paychecks. It's what makes the department run. Is it really an option? Do they love doing grants that much? You know, but really most of them are not that less willing to submit. And Bob is going to guide us through some concluding thoughts.

BOB DECKER: Well, we just showed you the tip of the iceberg, and we really just want to tantalize you a little bit with some of the results. I don't think we understand them clearly. But, you know, the FDP faculty are an incredible, university faculty are what drives this country. The freedom of our institutions to do research and the support from the federal government to conduct this research is what made this country great. And

now I'm pontificating, but since I have the microphone, I can at least do it for 30 seconds.

And we want, the faculty, and I'm sure all the research administrators and all the federal agencies want to ensure that this process continues as successful as it has been in the past. So we probably need to make some changes or at least we need to address the questions that are affecting research productivity. And the results of this survey appear to indicate that individual faculty spend a substantial percentage of their time on tasks that are associated with federal grant management.

And the first question I think the FDP has to address is this just part and parcel of the job description or can we improve efficiency by adjusting the system to work better for the faculty. And, of course, the last question is, you know, how can time be better allocated and what mechanism do we have. And I think that the final report which we will submit in May will make some significant recommendations in this regard.

Now in conclusion, none of this could have been done if the FDP didn't exist. There is absolutely no other forum through which this kind of data could be collected. And I want to thank all the research administrators who had a horrible summer collecting these databases. Without you, this would not have been possible. We wouldn't even know how to begin to start without your effort, and we really appreciate it. It has provided us some phenomenal insight into how our faculty function.

Now it's unfortunate that some of our faculty felt the burden was a burden, but that's probably inevitable. And a reasonable number of faculty felt the burden was spam, but that's what happens when you work on the web these days. But in conclusion, I want to thank you all because you're all part of this process.

And I think that the data we've generated is going to be very interesting to analyze and I'm looking forward in the spring to presenting you a final bit of information and maybe some recommendations for how we might alleviate what the faculty perceive as an ever-increasing amount of time that they spend away from the bench.

Now obviously some of this time they have to spend, but perhaps they can get help managing the rest of it so that they can be more efficient. We're certainly willing to take a couple of questions. You'll have to realize that we've just collected this data or gotten this data into shape in the last couple of weeks so we haven't looked at it that closely, but I'm willing to entertain a few questions. Thank you. Yes?

PARTICIPANT: I have a concern about the data . . . as a faculty member, I'm sure some of these issues will come up in the faculty discussion, but I wanted to bring it up while the administrators are here and particularly since the federal agency reps are here as well. I'd be really concerned about giving these data in the aggregate because when you say that 57 percent on average of our time is spent on active research, I think there's going to be a tremendous variability by field.

BOB DECKER: Sure, sure.

PARTICIPANT: And as a researcher in the health sciences who deals with IRBs and I know people who deal with IACUC issues, we spend a lot less time. So I would hate for the federal agencies to say everything is fine, you know, if you can spend 57 percent of your time on active research, that's great. I think you really have to come back . . .

BOB DECKER: Well, the question was phrased that, when all of us submit a federal grant, we put down a percent effort that we're going to commit to that grant. Our data is based on what percent of that effort do they actually spend on active research. I mean, the government is funding us to do active research. Are we really fulfilling that obligation, and the answer to that question is probably not.

PARTICIPANT: We're fulfilling more than our obligation . . .

BOB DECKER: Well, okay. You could look at it in that perspective. Yeah, we plan to break it out. That's why we wanted as broad a spectrum of disciplines that are funded by federal agencies, so we could address that question, because we have, we realize that faculty in different disciplines have different kinds of issues they have to deal with in managing their federal grants. Okay, you can digest and you can cogitate a bit on this. We will be back in May to give you some more precise data. Thank you.

JOE KONSTAN: So we will resume with our next session at . . .

NANCY WRAY: Yeah, we're running a little bit late, as you can see, so we may shorten the break and give you maybe just about a ten-minute time period for a break and then move on to the next session so that you don't lose too much time with concurrence. Thank you.

Friday, January 13, 2006

NANCY WRAY: Good morning. Let's try to get a seat. We have some very important sessions to get started on. And I do have a couple of announcements that I'd like to make before we get started with Belinda's presentation. Number one, yesterday, as a result of yesterday's meeting and some negotiation prior to the meeting, I wanted to announce that we have two new co-chairs of the Audit Task Force.

John Bane from Harvard has left to go on and try some new adventures, and I'm very pleased to announce that we were able to have two very good candidates come in, and that's Greg Thompson from Florida State, and it's nice to have someone from Florida, the originator of the FDP, on, co-chairing a group. And also Lynn Johnson from Colorado State. So thank you both for taking on this new initiative. And already they have a demonstration to propose to us in the next meeting, so we're very pleased with them taking on.

Another point I wanted to make is that, for those of you that were in the Terms and Conditions meeting yesterday, there were some handouts by Jean Feldman. We made additional copies of those handouts and they're sitting on the registration table, the end of the registration table. Feel free to take those. If they're out, contact David Wright and we'll see about getting some paper. These are not to be put up on any

website yet. OMB has not cleared those for a public website, but we can have paper copies.

I also just in closing want to say, those of you that do not want to take your notebooks back, the group will be collecting those notebooks at the registration desk as you leave so that we can recycle them, and I would really appreciate that. Okay. I think those are all of my announcements. And now it's my pleasure to introduce Belinda Seto from the National Institutes of Health. She's with the National Institutes of Bioimaging and Bioengineering. And she wants today to come and talk to us about conflict of interest and some work that the research business models group is doing in this area. Belinda.

BELINDA SETO: Good morning. Thank you very much. I want to give a special thanks to the organizer for accommodating my changes in schedule and so on. This is one very flexible group. When the organizers can change agenda in the last minute, you know this is a flexible group.

The research business model, I know this audience is very familiar with this. And in 2003, under the leadership of Geoff Grant, who is the chief ambassador to this activity, went out and held several group meetings, regional meetings. And the purpose of those meetings were to seek public input as to what should be the focus and the interest and the things that bothered the institutions the most that this group may begin to tackle.

And one of the common themes has been the inconsistent federal regulations, federal policies, and how we do things that drive you crazy. And the goal of this was to get some consistency . . . across the federal departments. So a working group was formed to address this particular topic, financial conflict of interest, and I'm very grateful that some of the working group members are, in fact, here, Joanna Rom from NSF, I know Mark Herbst from the Office of Naval Research, and there may be others that I overlooked. But there are a significant number of federal departments involved in this working group.

Our goal is to develop a core policy across that the federal department would consider and apply to their grantee institutions, keeping in mind that when I speak as someone from the NIH, you might immediately think, oh, the NIH financial conflict of interest that applies to the federal NIH employees. That's not what I'm talking about here. This is financial conflict of interest for the external, the grantee institutions.

Our immediate goal was to address the core policy based on the experience, the practices, the knowledge base that we've had from the PHS regulation and from the NSF policy. And as a first step it seems to make sense to at least look at these two documents and try to harmonize what's the differences between these two. And I will go through some of those issues in more detail.

So in terms of the federal-wide core policy, as I said, the aim is to be the common denominator across the federal departments. I don't like to say that it's the common lowest denominator, but it will allow, the commonality is such that it will allow institutions and agencies to build on that based on the needs, for example, the risk of the types of research such as clinical research.

We also at the present time, the NSF and PHS regulations have several components in their regulations and policy and I've described them here. First of all,

define what is financial conflict of interest, the applicability of these regulation policies, the policy requiring institutions to have written policies in place, written and enforced policy, the designation of responsible institutional representatives.

It could be a review, conflict review committee. Disclosure of significant relevant financial interests. And the reach-through to consortium that have relationship with the primary grantee institutions, addressing conflict of interest and how to manage them by citing some examples, describing examples. Finally the reporting and the record-keeping requirements.

Now the current policy in PHS is, was issued in 1995, and so was the NSF policy. Both of them really built on the principle that research must be conducted, reported, and analyzed in an objective way by individuals who are not influenced by the financial entanglement. And the principle is upheld in both of these policies. And to the degree that we know about it, the institutions, the grantee institutions that are out there, really don't have the problems with the principle per se, but it's the operating practices and the procedures that, inconsistent between these two that tend to make your lives difficult.

The PHS regulation on research objectivity codified in 42 CFR says that promoting research objectivity in research by, in the grantee institutions, by establishing standards to ensure that the design, the conduct, and the reporting of reporting of research funded under the Public Health Service grants or cooperative agreements will not be biased by any conflicting financial interests of an investigator.

Now then I'm going to flash up here, the NSF policy. There are very fine nuances that are different between these two statements. A conflict of interest exists when the institution's reviewer or review committee reasonably determines that a significant financial interest could directly and significantly affect, again, same as the PHS regulations, the design, the conduct, and the reporting of NSF-funded research activity or educational activity, as that is also the NSF purview to support.

Now the difference between these two, as I indicated, they're really quite subtle if you just read those two statements. Both of them, as I said, support the principle of research objectivity, but where differ in the procedural elements is in the NSF, if identify who makes the determination, the institutional reviewer or the review committee, and that there's also the issue of does this policy apply only to disclosable financial conflict of interest. And the NSF policy also considered the impact of the conflict research, directly affected, predictably affected or significantly affected.

Another issue that, besides the definition of differences, another issue where procedurally that differs between these two, the PHS and the NSF, is the applicability of the policy. For the NIH, it requires all grantee institutions to have a written and enforced policy and an administrative process to identify and manage, reduce or eliminate conflict of interest. The grantees, however, receiving SBIR . . . except from the PHS regulation.

Where they're different with the NSF is that NSF sets a threshold level that grantee institutions employ less than 50 persons in the institutions would not have to have a written policy or enforced policy in the institutions. So the threshold is 50 employees or more, whereas the NIH regulation does not have a threshold level in terms of having the policy in place.

The reporting requirements, before spending any NIH or PHS funds, the institution must inform the grants management office of the existence of any conflicting

financial interest that it has identified. We don't, of course, as you know, require that you send us the detailed financial conflict. We just want you to tell us that you have this, identified this interest yet managed to reduce or eliminate the conflict. And report on subsequently identified conflicts within 60 days and make the information available to the NIH upon request.

And we actually have exercised this last bullet. As you may know, some years ago there was a publication from an investigator at Stanford University stating to our horror at the NIH that some of our top funding institutions do not have written policy in place. And this, of course, received a great deal of attention, what do you mean, and so what NIH did was to exercise this last part of the regulation and ask our grantee institutions to send us their written policy.

And it was on this legal basis, this regulatory basis that we were able to analyze all of the policies that were submitted to us. And lo and behold, we found that they all have the policy. But when she conducted the research, depending on whom she interviewed, whether it was at the university level or the medical school level, they weren't aware that there wasn't institutional-wide policy or that medical school, as the regulation allowed, to have their own policy that's maybe different from the university-wide policy. So we resolved that situation.

The disclosure requirements, at the time of proposal submission to the NSF, investigators must provide to their institutions all their required financial disclosures and during the period of the award update the financial disclosures annually or as new reportable conflicts occur. Now for consortium participants, there is, in the current PHS regulation, the approach is a reach-through approach.

In other words, if an organization performing federally supported research flows any of the federal dollars to research organization as sub-awardee organization, then it requires that sub-awardee organization to have financial conflict of interest policy as a condition of receiving the funds as a sub-award.

Both the PHS and the NSF policy provide common management approaches to handle, to resolve financial conflict of interest. These are examples only, and I describe some of these here, disclosure, of course, as you know, at the institutions you know very well that that's a, at least a minimum first step, is to have disclosure, and monitoring of the research by independent reviewers.

For clinical research, this could be in the form of a data and safety monitoring board. Modification of the research plan to alleviate, to reduce, eliminate the conflict. Or at a higher level, disqualify the investigator from participating in the affected, the conflicted part of the research. And even taking it at a higher level would be to divest the conflict of interest, financial interest. Or at, I think a very stringent step is to sever the relationship that created that conflict in the first place. So as you can see, these are a gradient, going to more and more stringent steps.

Certification, both the NIH and the NSF require applicant institutions to certify that they have written and enforced policy at the institution. Now first step, actually the first one is my present step. I'm seeking input, the working group is seeking input from you. Tell us how these two policies, both the NIH and the NSF, working in your institutions, what drives you crazy, what you like, what you don't like about these.

And our hope, our plan is to issue a request for information, an RFI, to address the specific issues that I described just now and also on any other issues that we

haven't, the working group hasn't thought about or addressed. And the request for the RFI would serve as a prelude and advance to proposed rule-making.

So as I said, some of the issues that we have talked about in the working group are definitions between the two policies, the differences, the threshold of applicability, the reporting requirements, and also institutions, I don't know how many of them currently do that, conduct formal risk assessment that based on the risk have a gradient of applicability in their institutional policy.

So for example, if there's no human subject research ever conducted at those institutions, do they need the kind of level of monitoring, the level of independent review of research that one would have when, if human subject research were involved. So thank you for your attention. I want to reserve a lot of time to allow you to think about it and also share with me your thoughts as we move forward before we issue the RFI.

NANCY WRAY: Are there some comments?

PARTICIPANT: Good morning. My suggestion might be to consider raising the threshold. It, \$10,000 was ten years ago. And I know that there was a lot of confusion when the NIH came out with the internal \$15,000 threshold. So you might want to think about syncing those together perhaps . . .

BELINDA SETO: Okay. So you're talking about the minimum threshold, not the threshold for applicability.

PARTICIPANT: For reporting.

BELINDA SETO: The 50-or-more rule that NSF has.

PARTICIPANT: No.

BELINDA SETO: Good point. Thank you. In fact, NIH raised it to, the diminimus, is because today it's \$10,000. Well, \$10,000 is still a lot of money to me, but for others it may not be.

JOE KONSTAN: Yeah. I mean, take my comments in the spirit that I think this is a magnificent example of what administrative burden is about. We have a very small number of people who do something wrong and therefore huge numbers of people are inconvenienced to cover for the small number of ethical lapses. And I think part of the problem here is there's no in proportion to what. All of us have conflicts of interest.

If I did pure math theory, which I'm not qualified to do, funded by NSF where I promise there would never be an application or ever be a company interested in it, I would have a financial conflict of interest not by these guidelines that the chances of my getting more summer salary in the future depended on how many publications I get and whether I graduate students. And for me, that would be more than \$10,000 worth of financial conflict, but that's ruled out.

And what I would love to see somehow, and I don't know that this is feasible, is something that says given that we know that everything people do in life is conflicted by

the normal cycle of motivations in this world, by future grant applications, the desire for tenure and all of this other stuff, how can we identify the conflicts that are larger than the conflicts we already accept in everything else.

Moving up from \$10,000 would be a good step. Looking at it as a percentage of somebody's net worth, somebody who is well toward retirement and has a portfolio of equities that suddenly, you know, it's not surprising that they might have \$10,000 or \$15,000 or \$20,000 in an IBM or one of these days it might have been an AT&T or something else, and the question is, in the context of, you know, a million-dollar retirement portfolio, is that a conflict of interest or is that just a normal balanced portfolio.

And I'd love to see some sense of proportionality, if not encoded in the rules, because I know that's hard, allowed in the rules so that the few institutions that would take this on could model some examples of, yes, this is a financial conflict, but it's negligible because in proportion to the other environment of conflicts it just doesn't stand up.

BELINDA SETO: Right. Your point is very well taken. And in fact, the working group has discussed this a lot. And you cover a lot of points in your comments and I really very much appreciate it. You raised the issue about intellectual conflict of interest. And I tried to focus, at least for the working group, on financial conflict of interest. But the proportionality comment is very important.

And for a moment, when looking at this auditorium, I thought, I wish that NIH, that comment was raised at the NIH intramurally among, in reaction to the regulation that now applies to federal employees. Well, for a few people why are you punishing all of us. And so this, I'm hoping that we could have a core policy and that implementation of that at the institution level would allow reason to prevail. You all laugh.

DICK SELIGMAN: Unlike Joe's very lofty and scholarly view of conflict of interest, I have a much more sullied picture to share with you.

BELINDA SETO: All are welcome.

DICK SELIGMAN: I'm from Oklahoma State University, by the way. That's not true. Two observations. One, even though in both the NIH regulation and the NSF policy there is talk of eliminating conflicts of interest, I think that as a practical matter it's virtually impossible to eliminate them unless we build electronic fences around our campuses and lock people in and prevent others from entering.

Second, from the point of a view of a somewhat lowly research administrator, I think it would be extremely helpful if the federal government could come up with a common set of conflict of interest requirements. It is not driving anyone crazy, I think, but it's perhaps annoying. I think it would be more accurate to call it an annoyance that there are different requirements and different standards.

And it's very difficult to implement an institutional policy that adequately addresses all of the differences. And so what we typically end up doing is developing a policy that tries to go to the lowest common denominator, which may, as Joe pointed

out, put a lot of people through a lot of unnecessary work just because there were a few mis-grants somewhere in the past.

BELINDA SETO: Right. Again, I very much appreciate the comment. And the idea for this is really the central objective of our working group, is to try to get at that common denominator and that much of that still requires at the institution the reviewers, the review committee to look at these very much case by case. And that actually is where reason hopefully will prevail.

I absolutely agree that we don't want to put an electric fence around the institutions because, on the one hand, we have the . . . that encourages investigators to have those interactions, if not relationships, with the private sector. And that has actually provided a lot of, much of the economic engine that drives the biotech industry in this country. And so how do you strike the balance when ultimately the principle, the goal is that the public trust the science.

And, you know, very timely, I was riding on the Metro looking at the Korean human stem cell saga unfold yet again today, and that, and not only while the Korean government feels very ashamed there's erosion of the national pride, for us as a scientific enterprise, it erodes the public trust.

You know, we were held high esteemed, and I daresay in Washington, D.C., higher esteem than Congress, might I hope, that, you know . . . and so I, so I really, the goal, the principle that we want to at least, that the publication, the scientific publication and the scientists are trust the citizens in this country, and that what we want to do is to make sure that when we peel the onion of the scientist relationship there isn't something that smell fishy in the financial relationship, that they get financial rewards from those relationships. So I think we all agree on the principle, as in practice, how do you do it without making you annoyed.

PARTICIPANT: Can I just add a point of information in terms of what Dick said. I think the framework we've been using on the committee is talking about managing risk rather than eliminating risk. And I think that's real important, and disclosure being one of those tools. So there may be other factors in the government, like IGs, who want to eliminate risk, but I think we're trying to be . . .

PARTICIPANT: . . .

PARTICIPANT: Even managing conflicts of interest as opposed to eliminating them.

ANN POLLACK: Hi. I'm Ann Pollack from UCLA. And I have been working for many years with trying to help the people on our campus both understand and helping the campus implement and then refine and update the existing policies. There's a lot of confusion, and I would hope that the working group could help us in the research community by simplifying things.

On my campus and within the faculty and staff who call me and ask questions, I think there's confusion on many levels. One of them is that the word significant is used in a lot of different ways, in a lot of different places, and a lot of confusion over the difference between the significant financial interest that needs to be disclosed and . . .

another context, a significant conflict of interest that needs to be managed, reduced or eliminated. So if it's at all possible for somebody to go through and make clear distinctions between disclosable interest, disclosable financial interest, and any resulting perceived or real conflict of interest, I think that would help under a lot of confusion.

Another part of the confusion is that, in their infinite wisdom, the people in our system-wide office who took the federal policies and made it into a system-wide policy so that the campuses could create campus-specific took, well, into effect all, the notion of the flexibility that the various federal regulations give us, which we appreciate and applaud. On the other hand, they created their own set of definitions.

And so in an attempt to better explain to faculty what they felt needed to be disclosed, they came up with their own notion, which they called relatedness. So if you, faculty member X, have some financial interest which meet the level, the threshold for reporting, in an outside organization that you think might have some relationship to the predictable outcome of the funded research, then report it.

Well, as a result, we have massive confusion that we've never been able to simply explain what we're asking for. If you're doing research that might lead to a new drug development, we really don't want to know how many shares you have in a tire company or Wal-Mart. But we do want to know about . . . I don't know that there's a clearer way of explaining the universe. But anything you could do to help would also be very appreciated.

And my final comment is that the last of your suggested management techniques is the severance of the relationship. I'm not really a stand-up comedian, but I will tell you that with straight faces people have said my financial interest stems from my spouse's employment or my spouse's holding the shares, does this mean I have to get a divorce.

BELINDA SETO: Again, if I close my eyes for a moment, I would have thought I was now in the NIH auditorium when this topic was discussed. And that's where in the implementation as a committee that those would have to be handled. We couldn't and I cannot imagine spelling those out in the federal core policy. But your point is very well taken in that there is interpretation.

And when you mention significant, it is related to the comment about the diminimus, and that's what we're striving to see, if there could be some commonality. And we were very sensitive at the NIH that we recognize our regulations setting a diminimus is going to have implication. It's not NIH, I was going to say it's not fenced in, but, yes, we are fenced in.

We do know that intellectually we have an impact in terms of our own financial conflict of interest regulation for the employee. It won't affect the grantee institutions. You will look at it, what do you mean by significant, what do you mean, how do you actually interpret the proximity of relationship. Those things will actually have to be in the review committee where, unfortunately, I have to say, would have to be interpreted case by case.

CHARLES DECEDUE: Charles Decedue, University of Kansas. Relative to the last comment, it would be helpful if you could provide us best cases of mitigations that do work or that are at least palatable. The policy is a part of what you must do, but at the

end of the day, we have to mitigate conflicts. We're not going to eliminate conflicts. And it would be helpful, I think, to most of us if we had some best practices to follow.

BELINDA SETO: That's our next step. And we could do publications and resources about best cases, our best practices and also case studies. I for one learn by case studies, even though, you know, you have to extract from each case what's the lessons learned, what's the principle and philosophy there.

PARTICIPANT: I'm an investigator and I'm a member of the conflict of interest committee at my university and also do FDA-related research and work with the IRB. One of the things I want to point out is that the universe that you are talking about is a small part of the conflict of interest universe that the investigator and the institution actually live in. The rules that you are talking about are only the NIH-funded research rules.

The FDA has a completely different set of rules. The NIH has also given a different set of rules for what the IRB must consider in terms of conflict of interest. So the investigator is living in a world where there are three sets of rules that they must follow, which in many cases are conflicting, not even not congruent.

And I would urge you as you look at the NIH process to harmonize not only within the NIH, NSF funding arena, but also consider the charges that you're infrastructures are giving to the IRBs for what they must review and also work with the FDA so that an investigator is following one set of guidelines, rules, and principles and not trying to follow three which cannot be matched accurately.

BELINDA SETO: Right. And a very good comment. But we're taking it one step at a time. I also on the federal side probably are your counterpart in that I was involved in the FDA, the disclosure after the IND and so on. We actually got the FDA to come to the NIH at the table and see if we could resolve that. The diminimus level is different. The point of disclosure is very different.

And the FDA said, but we are the FDA, we, and the, and I don't mean that pejoratively. At NIH and NSF, the policy is applied when the research is conducted in real time, whereas the FDA is collecting the information retroactively, after the, retrospectively, after the research is already finished. And actually my FDA colleagues would tell me they have a hard time getting that information from the investigator because what's their obligation, the work is done during the application stage.

And that, your point about the human subject regulation, what applies to the IRB, what applies to the, in the bioethics arena, the guidance, and . . . was very careful to choose words that that's really guidance and it's more a, it's guidance, though it doesn't carry the weight of the regulation and policy. But that doesn't, I'm not minimizing the fact that there's these three pieces here that are not consistent.

PARTICIPANT: It may be guidance, but it's guidance that is learning IRBs to look at diminimus levels that are pizza delivered to your conference, the pen you pick up at your professional society meeting. And diminimus levels which are totally different than those that you are talking about and talking about raising, and from the investigator

point of view, managing the multiple sets of data that must feed all of these pieces is very, very difficult.

BELINDA SETO: Right, right. I absolutely agree. But we're attacking this, we're tackling this one step at a time . . . the conflict of interest is huge.

PARTICIPANT: I appreciate that, and I think that that is a very important step. But I would also urge you to keep your eye on the long road to be traveled rather than just the next three steps.

BELINDA SETO: Yeah, see, I was hoping to fly under the radar screen when I said, you know, your institutions have the flexibility to calibrate . . . support human subject research, clinical research. You can obviously have to have measures in place to look at that facet of research. And I was hoping to dodge the bullet, that not to have to talk about the DHHS guidance on IRB and human subject research, but obviously we're begging the question when we develop the core policy, what's outside of the core.

PARTICIPANT: Good comment. Thank you.

PARTICIPANT: Some of us may remember back in December of 1986 when Louis Sullivan issued these rules for comment, that they were initially only applied to clinical trials, and subsequent iterations then broadened that to basic research. One of the concerns that I have is that we have, in a sense, the same criteria for different kinds of risk areas.

And I serve on a conflict of interest committee at Penn and it seems to us that we treat, we develop management plans for basic research, but we're much more stringent when it comes to research that involves the use of human subjects or clinical trials. And I'm wondering whether that aspect has been given any consideration, although there seems to be more road to be able to permit rather than deny the ability to do research under a non-human subjects research plan. And I'm wondering, has any consideration been given to that . . .

BELINDA SETO: Absolutely, in the working group. And I see Mark back there nodding his head because he's been the strong advocate in the working group about risk assessment, that that's where we really, in practice we have to apply measures that is based on risk. Where the human subject research involved is there's an additional dimension here.

It's the safety and welfare of the volunteers of the subjects in clinical research. Even in the, and coming from the institute where I reside right now, there's a lot of basic research development devices that could have financial relationship that jeopardize objectivity of that result.

Yes, it's true that there's no human being being harmed, but the scientific findings, the conduct, the result, and, again, the reputation, the trust of the scientific enterprise could be jeopardized if we didn't manage that. So the short answer to your comment, your question is that, yes, the risk and the calibration of those risks and how

we apply this core policy or a more stringent policy has been discussed and we'll continue to do that.

CAROL BLUM: Hi. I'm Carol Blum from the Council on Governmental Relations, and we've certainly watched a similar effort with the misconduct policy, ACOR and each of the agencies bringing it up. And while I don't have a perfect solution for it, I would urge you to think about the language that is used to recommend to the other agencies to implement the policy.

When we saw the misconduct come up at different organizations, there would be small changes of language that had a significant impact on the consistency of definitions, the what significant means or what. And then a tendency to assign or give the institution its flexibility to do what it's supposed to do, but then the imposition of like a second tier of review that can become very complex.

And the relationship then with the department or with the agency became much more restrictive and required much more of the organization and relied on them to approve and review and monitor in a way that it was not our understanding when we saw the core principles that that was going to be the way it fell out. So as you come to an agreement on the core, how you recommend to your colleagues across the federal agencies to implement this will be equally important as you put the policy . . .

BELINDA SETO: Good point. Thank you.

NANCY WRAY: This will be our last question. Thanks.

JOE KONSTAN: I'll even make it simple enough so you don't have to answer it. A really simple suggestion. Invest a bunch of time in a preamble to get rid of the idea that conflict of interest is what's bad, because that's what the attitude is on most campuses. It's that, ooh, you have a conflict of interest, you've already done something wrong.

In view of . . . in view of what we're trying to do for the nation's economy, the preamble should say conflict of interest is an inevitable consequence of an engaged researcher who is attempting to work constructively to bring their research out into the economy and into the marketplace. We have a national interest in managing that conflict to avoid adverse effects on research subjects and on research results. But let's start the discussion with the idea that, hey, if you're before a conflict review, good work, you're out there and engaged in the community, now let's solve the problem.

BELINDA SETO: I love it, to have a talk that ends with applause that's not even my own comments. Thank you very much. But, yeah, in fact, the preamble has been discussed, a draft, but that's exactly what we are trying to strive at. And on the human subject universe world I live in, I tried to say, there is never a research that's no-risk. We'll never get to that end point. So let's not set ourselves up of absolute zero, but it's the proportionality issue, the comment that you raised earlier. Thank you very much.

PARTICIPANT: Can I just ask, what's your timetable for the request for information?

BELINDA SETO: So my earlier comment that Jeff is an ambassador, he's also the taskmaster on this, and he imposes timetable on me. So whatever he, I'm certainly, we have been at this for over a year. And part of that is because we put the activity on hold when NIH was developing its own internal regulation and we wanted to know what that final product looked like.

But now the working group has picked up steam, so I'm hoping that we will have something out in a few months. Is that loose enough? All of your comments are very much appreciated and very valuable. I will convene the working group and I'm sure we're going to go through all of these points. Thank you very much.

NANCY WRAY: Thank you, Belinda. Okay. We're going to move very quickly along to our next topic. As many of you know, are aware, the Department of Health and Human Services Office of the Inspector General issued a draft compliance guidance for recipients of PHS research awards. We have an opportunity to comment and the Executive Committee felt very strongly that the FDP should provide some comments back on this draft guidance.

So today what we thought we would do is run it in a sort of an open forum to elicit your comments and also to encourage you as individual institutions to respond to this draft. Geoff Grant is going to facilitate this for us. I think you all know Geoff, and those of you that don't, he's been a friend of the FDP from the very beginning. He's worked at the NIH, Stanford, and is now at the National Science Foundation but on assignment to OSTP with the research business models.

And Geoff is going to start the discussion. To facilitate the comments, Joe Ellis has kindly agreed to be one of our microphone conveyors to make sure that we can get the comments in the back of the room so that you that are way back there, that are hiding, we can capture your comments and make it easier for you to get to the microphones. So without further ado, Geoff.

GEOFF GRANT: Thank you, Nancy. And good morning. I'm sorry I couldn't be with you all yesterday. I had the good pleasure to be at another Academy meeting, at the Keck Building rather than this building, the beginning of the new committee on science and security, so we were dealing with export controls among other things. I still haven't quite figured out what it was I did in my adolescence that stuck me with this problem, but I wish I could just apologize and get past it.

So as Nancy said, I'm really going to be the facilitator, an honest broker for this discussion, and not interject any opinion. And I figure I can last about five minutes in trying to do that, but this is an opportunity for the FDP as an organization to collect comment on the HHS guidance on this subject. And I think, as I understand from Nancy and Joe, that they will be very careful as they convey this summary of your observations to not unintentionally suggest that this is also the position of agencies represented here, but rather just the collective outcome of this discussion.

So I want to lay out one ground rule. I don't mean this to be absolutely inhibitory, but I think those who comment ought to have either thoroughly read and analyzed this HHS publication so that we get informed comments or have just a smidgen of Irish heritage so that no matter whether you read it or not, you're obviously fully prepared to

comment. That's been my personal guideline for participation and research administration policy development for a long time now.

NANCY WRAY: I will, I'll make one comment. For reference, the Federal Register Guideline is in your book. It's under tab six, probably at the end of tab six, just for reference and any questions. Seven.

GEOFF GRANT: Yeah, just to get an idea, how many people have read this before? Okay. That's not bad. How many of the faculty here have read it before? Okay. Fewer in number. You all obviously have more important things to be reading. And as Nancy said, Joe is going to kind of roam the back here. I encourage some of you that don't want to come all the way down to the front to collect some comments and share the microphone. Others if you don't mind, step up to the mic.

Just for the purposes of discussion, I thought we ought to divide this topic into these areas or subtopics, if you will, because you may have some observations just about the content of the elements of effective compliance programs. If you've read it and, you know, whether they are gaps or areas that you'd like to see clarified or things that you think that are off the mark or what have you. Those are different than the areas of risk or concern that HHS also points to in the document.

And I think it's worth making a little bit of distinction among those. And you may feel, for example, that there ought to be some additional areas or those aren't the right areas or there shouldn't be any areas or whatever the nature of your observation may be. And then finally, there is somewhat more unspoken, kind of a policy process at work here, and it's interesting to think of some parallels between conflict of interest and research integrity that were mentioned. But that is, where are we on kind of this continuum of policy development.

HHS refers to this as guidance to institutions, and it's in the context with regard to the use of PHS funds. So it raises some other questions then of, well, what happens because is this really guidance, is it, you know, my term, effective practice, that it's just to help inform what institutions and administrators and faculty do, or has it become something more than that. And in fact, does it perhaps even unintentionally rise to a level of a standard or should it perhaps be then more formally declared as official policy. And then I think another element that surfaced . . .

[Tape change]

GEOFF GRANT: . . . one of your points is how do you integrate this guidance, if you will, into what may already exist in some institutional system or program. Great. Andy.

ANDY RUDCZYNSKI: We discussed this document in our university, what we call a research compliance group, and one of the, the consensus, and this includes the vice provost for research and our deputy council for compliance and a variety of other folks. And it seemed to us in terms of commenting on this, which we intend to do, that it's very difficult to say the principles aren't good ones. In other words, in many sense, they're common sense.

They would be fundamental aspects of a compliance program. They do have, as Jane indicated, their genesis several years ago in the sentencing guidelines and so forth. But I think that moving beyond that is very problematic for most institutions. You know, and the comment has already been made that all the sections that deal with identifying and expanding or expounding on the risk areas are technically incorrect. I mean, it's like they only read part of A-21 and didn't read paragraph D when it comes to . . . reporting. And to have that in a document I think is inappropriate for a guidance document because it raises issues.

And then we think, I mean, we will be commenting on the compliance program itself. I mean, the whole tone of the description is written in an imperative language, that is, you should do this and you should do that. And our concern is that while you may, it's nice to have guiding principles, to go beyond that we'll then become, and you've indicated that it may become a de facto standard when there is either, not likely a programmatic audit, but certainly when you have an audit from the OIG for a variety of different issues.

If there was a misconduct case, you know, what kind of compliance mechanism did you have and why didn't you find this out sooner. And that would lead into what is your compliance program and does it have these 12 elements that are, you know, whatever the number of elements that it has. And I think this is a very dangerous road.

We recognize that it, I mean, this is a little bit like, it's undeniable in terms of coming forward because of the heightened emphasis on accountability. But the prescriptive nature, I think, is problematic. And I don't think the OIG has sufficient expertise, if this is any evidence within it, to be able to, to suggest effective compliance programs.

I mean, organizations like the pharmaceuticals and COBRA and others have written what are effective management practices that could serve as models for compliance programs. But each institution should be able to pick and develop a program that is most conducive to its particular culture. So I think that would be a major comment I think that the FDP should make. Thank you.

GEOFF GRANT: Good. And Joe has faithfully captured all of that. Andy, you would say, if I understand you correctly, you would suggest not publishing any areas of risk. Is that your, on that particular point?

ANDY RUDCZYNSKI: Yes, I would, because I think certainly areas of risk are evolving. You know, today somebody might think it's effort report, whereas in actuality it may not be.

GEOFF GRANT: It's obviously export controls.

ANDY RUDCZYNSKI: Export controls is another one. And so it's, and that's a moving target because we still haven't heard from BIS and so forth, so we don't know what it's going to look like next week when they, or whenever they issue the new requirements. So, yes, I think it's a danger to set it in stone. And I think institutions ought to be able to assess for themselves what are major areas of compliance.

GEOFF GRANT: Good.

JOE KONSTAN: I do encourage you as you finish a comment to take a look and see if the spirit of that comment has been accurately captured and, of course, we'd be happy to take corrections offline if you prefer.

GEOFF GRANT: Any other comments just with respect to the content of what HHS has proposed?

GEOFF GRANT: These things are all of a piece. Okay. Any other comments on content? How about then those that might want to, we've got a couple comments obviously on these areas of risk or concern, but any more on that in particular? No.

PARTICIPANT: I assume this qualifies as content. The implication that an investigator somehow misbehaves if their active and pending support commits them to greater than 100 percent. That's clearly a content issue that I think the OIG just simply didn't understand.

GEOFF GRANT: Okay. Very good. All right. Well, moving right along, how about the policy process, if you will, my words, that they describe this as guidance. We've heard a little bit already, you know, is it that or effective practice or does it become something more than that, does it become a de facto standard or should it perhaps be articulated more formally as policy. Anybody who'd like to comment on that? Yes, Jane.

JANE YOUNGERS: Well, I'll comment again. I don't think guidance says things like, as Andy said, should, you know, will, must. All of those words indicate to me that an auditor looking at this or someone coming in and reviewing something is not going to see that as guidance but rather prescription. And I think for them to use that kind of wording is absolutely incorrect in guidance.

GEOFF GRANT: Okay.

JANE YOUNGERS: And that's why we liked what OMB, OMB, you know, came out with that notice on writing guidance on guidance for the agencies, and that's one of the points I know that we made, is that this is a perfect example of a document that probably is not guidance but is prescription.

GEOFF GRANT: Andy.

ANDY RUDCZYNSKI: I just wanted to add that the section that starts out, the effective compliance program has in it the phrase at a minimum should include, so it signals that the expectation is greater than what's actually noted here. So I think that's, again, to emphasize the point about the prescriptive nature of the section is beyond just describing the principles.

GEOFF GRANT: Fair point.

PARTICIPANT: Geoff, I'd just like to, that's wonderful. I think that, I think one of the things that's been stated before but I think we ought to underscore is that institutions have, need to be able to work within their own governance structure to establish compliance committees, compliance mechanisms. And this defines there shall be a compliance officer, there shall be a compliance committee, it shall be staffed according to such and such.

And that may or may not fit your particular institutional organization. And so if you set out a general plan, a general, a notion of here are the things, here's the guidance, these are the general areas that you should be compliant with, that's one thing, but when you go down to directing us into how our institutions shall respond, that's not guidance.

NANCY WRAY: I'd like to add one comment to that, Suzanne, and I think it's very good. I'm thinking about some of the smaller research institutes that do receive these grants. To try to set up a program that's outline in this may be impossible for them from a resource area or just it won't fit into their environment. So I think that maybe a point that needs to be emphasized is, what is being prescribed here may really inversely impact the smaller institutions.

GEOFF GRANT: Okay. Any other comments along that line? We're talking about standards or de facto policy.

PARTICIPANT: I would agree with the other comments about the prescriptive nature of the document. My own personal experience so far has been discussions with our audit firm several weeks after this came back and they've already taken this as a prescription and indicated and asking me questions about how do PIs devote time in their proposals. And their national partner was trying to create a guidance document to update their audit plan for this. So it's already gone to that level. So I would agree that at minimum we should move to strike all those risk areas. It's just totally inappropriate.

GEOFF GRANT: Other comments? Yes.

ANDY RUDCZYNSKI: I was just going to put my Irish hat on for a second. I think that the, some of this is dangerous. I think what Joe was talking about emanates from Sarbanes-Oxley and I'm not sure whether, you know, there's a confusion here about things that are applicable under SOX to institutions which it's not applicable to and the corporations. And so the auditors might be applying standards that they're applying to corporations to institutions when they're doing their audits.

And I think that, again, that may expand it beyond the kinds of, the intent of all of this, but I think you'll see more problems in that regard, because already our auditors are saying you need to have codes of conduct and go well beyond the, I mean, there were certain codes of conduct that were required under A-110, but it's, it goes well beyond some of that. So we're, again, foisting onto institutions practices and policies that are not necessarily consistent with their governance structure.

GEOFF GRANT: Yes.

PARTICIPANT: I was going to ask, and more for discussion, how do you discipline, appropriate discipline a tenured faculty member? I mean, I was always sort of under the impression that we do something wrong, we give the money back to the feds and then we deal with our faculty members as appropriate for whatever our policies are. But it seems like the number seven item on there, the appropriate discipline on there, I mean, is that what we should all have been doing already or is that new? It struck me as more new than maybe it should have.

GEOFF GRANT: Anybody like to comment? Anybody ever discipline a faculty member before? Do we have some best practices in this area . . . you want to comment on that?

PARTICIPANT: My comment really is in concert with a lot of the previous comments. But I'm concerned that in addition to everything else that's been said, and as Andy just used the word governance, this really also prescribes an organizational structure that says you must have a compliance officer, this tells you what to do if you're a small organization.

It suggests that if you're a large organization you really should have one person who is at a certain level of the organization. It has really gone beyond any kind of policy or procedure or we expect you to have a written policy or a process into defining how, where, to whom it reports, and truly an unfunded mandate, including the part about the appropriate budgets, which is a lovely way of telling a university that you should do this rather than all those other things with your scare dollars.

GEOFF GRANT: Good. That's helpful. A little more response to perhaps on this point about discipline. Does anybody want to respond to that at all? I have an observation on that, but any comments, because this is helpful as a dialogue back and forth too.

PARTICIPANT: Yes. I would like to say something, and that is, that there are many university policies that, including the one that the University of California has for dealing with charges of misconduct of many sort against academic appointees, not just research misconduct, but violations of our own faculty code of conduct. But they're also cloaked in confidentiality. The federal misconduct regulations talk about confidentiality. The university talks about confidentiality.

And as a result, even though some of us may be aware of the fact that there's a disciplinary process and even an outcome, sometimes a settlement, rarely is that ever made public. To make it public, which some of these prescriptive guidelines tell us we should do, and to deal appropriately, is not just a cultural norm violation, but it would be a change in the way that a lot of universities do their business.

And that isn't to say there isn't some problem with that, because we have had many people say, to me and others, are faculty ever disciplined. And the answer is yes, but we're really not in the ability to say Joe Doe or Jane Q. Public was demoted because of X or, you know, the reason they left on early retirement really wasn't early retirement.

GEOFF GRANT: And I would just add, my understanding of it is that this really is one of the elements that comes from the federal sentencing guidelines. And they're saying in effect that there isn't any kind of consequence, maybe the most general and constructive term.

And if there isn't any kind of outcome or review of an individual transaction or event, then there isn't any import to the policies or program that an institution may have. So they're looking for consequence and they're looking to at least perhaps even confidentially learn that there's been appropriate follow through on some of those transactions. Okay.

The last suggestion I made just around structuring these comments was around what's the rationale attached to this or the underlying principles or what kind of outcomes do we want from this, and does this document articulate any of that. Are you comfortable and satisfied with that or would you suggest some other additional approach to that? No. You're perfectly satisfied with that. What is compliance? How do we recognize noncompliance?

PARTICIPANT: I'm not sure if this is the appropriate insertion point here, but this policy strikes me as very, much of a regulatory and perhaps punitive. In contrast to in my former, one of my former employments, we had the benefit, even though it was somewhat pressure-related, that we had an educational visit from the NIH to review our regulatory policies.

Again, it was a lot of work and effort, but it was a positive approach, helped point out some of our strengths, some of our weaknesses, but most importantly it provided us an opportunity to really strengthen our policies to meet the mandates of federal regulations and guidelines in a very positive fashion. I don't see this as being positive whatsoever.

GEOFF GRANT: Okay.

JOE ELLIS: Thank you.

GEOFF GRANT: Anybody else? Joe lasted more than five minutes.

NANCY WRAY: Perhaps one of the outcomes is what Carol has suggested, well, what we should suggest is the withdrawal of this document and that, to step back from it. So I think that would be one of the outcomes that we could suggest.

GEOFF GRANT: That's an outcome of the policy process, and I was asking maybe a little different question. Is what do you think they're interested in in terms of the outcome of the guidance. And there was an interesting discussion this morning around export controls and we're spending a long time admiring the problem, but not necessarily addressing a solution. And so somebody might say is there a problem here. And if there is, what's a different way to get to that outcome, you know, or a positive outcome.

JANE: I guess the thing that troubled me when the draft was issues a couple of years ago when this came out is what brought this on. You know, is there really something they believe that we're not doing correctly or not, I mean, I recognize that effort issues have been around. And you see, in the risk areas you see the effect of the settlements that have been made. But it's kind of like what brought it on. We have all of these guidance and rules, etc. already. Do we need another one? I just never quite understood the reasons they're doing this.

GEOFF GRANT: Okay. Very fair.

PARTICIPANT: One of the points that Minnesota is intending to make and our response is that, you know, most of our institutions have operational compliance departments and offices and that, and we didn't think that this document really addressed the fact that there's a lot of operational units who are doing their jobs in this compliance area, but that there may be, and they were trying to prescribe an integrated compliance office and being very prescriptive about that.

And I think that this, that the feds need to recognize that most of us are doing our jobs in this area and they should recognize, again, to support what lots of people have said, the institutions have to decide how they want to do it and not be so prescriptive in their comments. And you have to have an enforcement policy. Hopefully you don't have to use one, but you do need to have an enforcement policy, and we learned that at Minnesota.

GEOFF GRANT: Good. Okay. That's helpful. Andy.

ANDY RUDCZYNSKI: You were talking about outcomes, and I think one of the outcomes I think is already happening, and I think that that is that institutions are already in many respects taking very proactive steps in order to change the way they've been doing business. I think this isn't the galvanizing event. It was the event in 2003 that, and other even before that, activities that happened that galvanized institutions to, that they needed to manage and operationally have checks and balances on the way things are done.

And it almost seems like this is, you know, the horse is outside the barn and now we're telling you how to run the compliance program when actually all the precipitating events happened in 2003 and before that, that sort of work up institutions and the OIG and others that really needed to take a little sharper view of how the operations were working and what the appropriate checks and balances were that were built into those systems.

GEOFF GRANT: Thank you. Yes.

PARTICIPANT: Has the . . .

GEOFF GRANT: It has. January 30th. Yes.

PARTICIPANT: One of the issues I find that's duplicate in the sense that when I look at our faculty member, he does his IRB, sometimes depending on where he works he goes to . . . safety monitoring plan, and then if he goes through the GCRC he's got a subject advocate. And all of a sudden I've got more compliance officers than I've got faculty.

And the other thing, if you go to the NIH guidelines, it says the person who signs this agreement is responsible for physical affairs, he's responsible for the compliance, he's responsible for the legal. And what I've been finding out is OHRP visited our campus to give us, quote, some suggestions of organization. So obviously the president is going to follow his suggestions. We've had people from OPRR come down on an NIH site visit and they had suggested that our . . . be at a certain location or someone do it. And I think we were, you know, happy with that. But we get a lot of, quote, guidance from the federal government.

And one of the things that I see, once you get into an authorized institutional official who has all these responsibilities, but then we have people saying, well, you're too closely related to the IRB, you're too closely related to this. All of a sudden we're no longer in control. And one of the issues that we had, OHRP came down to our campus and said I wanted you to be removed from the, further from the research office. Two months later, we made the headlines under OHRP because the IRB did not communicate with the administrative office.

PARTICIPANT: I'd like to reiterate that. I'm wondering to what extent the OIGs have actually examined in any meaningful way the processes that have been put in place in a variety of institutions. And if they have, is this federal register document a shot across the bow indicating that they have, they don't like it.

The issue of being too close to the problem I think is an interesting one, because if you're not close to the problem, you never recognize the problem and it makes it virtually impossible to try to define whether you've got a compliance issue if you're too far away from it. And so it's sort of a catch-22. You're damned if you do and you're damned if you don't.

GEOFF GRANT: Okay.

PARTICIPANT: I think you're giving way too much credit, because I think you need to look, if you've looked, they have lots of these compliance guidance out there on their website and they all look very similar. So they've got a cookie cutter that they're kind of putting out there and then they do this financial side with ignoring all the IRB and all the other kinds of compliance issues which are far more robust and we're dealing with a lot more than they say. And I think it's more naiveté than, although . . .

PARTICIPANT: Nancy has probably already suggested this or thought of it, but would they like to come to Seattle and discuss this with us?

NANCY WRAY: We invited them to come to this meeting and were told that they could not come before the end of the comment period to a public forum. We will try to do that again, invite them again.

GEOFF GRANT: Debbie.

DEBBIE RAFI: Geoff, I want to try to talk about this in a very simple context, so I hope I don't, I appreciate your patience. I have to admit, I was a government auditor for seven years, and so, and now that I've been out of it for ten-plus years, my experience in the government has been that generally policy is reactionary, so I think right there we can safely conclude that this is a reaction to something. Now what that is, I think if you look at the details and the content, you can see a fairly strong correlation back to the settlements in the newspapers articles we've been reading in the front page.

There was also an effort to sort of beef up the compliance supplement relative to effort reporting and areas like that. So apparently there's a perception from the IG office that there's not enough adherence to the existing rules, and so they put out this guide, which I compare this to, sort of to the discussion we've had the last three years about . . . monitoring where, you know, the auditors are starting, the A-133 auditors were starting to ding the schools for not having . . . monitoring programs.

And then the schools would turn around and say, well, government, what do you want us to do, tell us how to define risk, tell us this, tell us that, give us what your minimum threshold of acceptance would be for . . . monitoring program. This is how the IGs think. So they think they're doing what the community wants. Now that can be debated, of course. But I'm not sure, you know, again, be careful what you ask for, you might get it.

GEOFF GRANT: Good. Suzanne.

SUZANNE: I think relying on the IG to settle this presents the problem that as we read the first definitions of the risk areas it's clear that somebody who wrote this didn't carefully read and understand or get guidance on what A-21 really says and on what is really expected when investigators are submitting proposals.

So I'm quite uncomfortable with people who don't understand and are auditing us against a document they don't understand, coming in and then telling me how to run my university. I mean, I would say, yes, please withdraw this. Several organizations with skilled folks have developed best practices. If you're not going to, if you want to issue guidance, then refer to those documents as standards of best practice and then take a big step backwards.

GEOFF GRANT: Yes.

PARTICIPANT: Okay. Well, thinking about be careful what you ask for, one of the things I'd like to ask is, is it reasonable to ask the OIG to look for resources that might help it put together some kind of guidance that could really be helpful, like there's this organization I heard of called the Federal Demonstration Partnership where they have meetings about this kind of stuff. And I, I mean, I do wonder sort of from a political point of view what might be a reasonable thing for us as an organization to do to try and encourage that kind of a collaborative situation.

GEOFF GRANT: That's helpful.

PARTICIPANT: I just want to make an observation on the comment that they could not come here during the comment period. The Department of Defense came to the table at the National Academies workshop on their DEFARS clause during the comment period, so I just find that kind of interesting. And then the other comment I have to make is that it seems like to me what we're seeing in all of this guidance and in these documents is they want someone to pin the blame on at the institutions.

I certainly don't want to be a compliance officer with that title at my institution if we're going to have documents like that out and, you know, out in the public domain. I had my staff working on a matrix to look at, to tie our roles and responsibilities to individuals, and it came back with X's in almost every block.

And what that means to me is compliance is the responsibility of everyone, and it's really hard to say that it's, you know, that one person, and particularly at our institutions, you just don't have the control to be totally responsible. And, you know, what we need is guidance on best practices. You're hearing that. And it's not who's going to get hung if we don't comply.

GEOFF GRANT: Good. I have a question. I'll kind of step over at least to the edge of just being neutral facilitator. I'll draw a parallel. I think it was Joe's point on conflict of interest, and that is, what's the level of materiality. And it's embedded in a question I raised about what is compliance or how do we recognize noncompliance, and what's the difference between maybe just unintentional error or incorrect follow-through on a requirement versus sloppy operations, you know, maybe just even a lack of procedures or material noncompliance with a significant federal requirement or fraud.

And there's a continuum there, I think, with a lot of points along the way that very quickly get wrapped under an umbrella of compliance. And I've spoken and written and held workshops on compliance for quite awhile and I'm just as guilty as the next person of, you know, over-generalizing that issue.

But I think there may be a need for some definition in this area and perhaps some materiality test of, you know, how do we recognize when we're really talking about something that's at the level of an infraction where it requires enforcement. Anybody want to offer some thoughts or observations? Have any of you struggled with that within your own institutions? No. Okay. Well, Andy. You get the final word, perhaps.

ANDY RUDCZYNSKI: I just, from a university standpoint, I think it's really, what you're saying it really a day-to-day practical question, I mean, how do you say, well, should we do something about it or is it just an aberration that happened that one time. And it's always a question of judgment as to how far you should push the tip of the iceberg.

In other words, you catch the tip of the iceberg, do you, should you be going down and digging out every single transaction that that person ever did or that department. And I don't know that there's a simple answer. I mean, it depends on, you know, if you really want to be bird-dogging this, and you'll probably go after every single thing. But then the question is, you know, what's the value of doing that and is there harm done to the sponsor or to the institution. So not an easy question to answer.

GEOFF GRANT: Winifred, you've really struggled with some of that in Minnesota with your departmental reviews and benchmarking. Any thoughts on that subject? You know, what's poor operation versus noncompliance?

WINIFRED SCHUMI: We do, well, what we try to do is in our day-to-day operations is try and inform people of what things they need to pay attention to and say, you know, look, we've seen in your financial transactions, for example, that, you know, you've got some issues, way too many cost transfers, whatever. And then ask them to analyze their management practices at their units.

And by and large, our departments are very responsive to that. I think that has improved compliance, in particular on financial. We did have a unit that did not respond to our increased, we have a level, you know, if you don't answer by such and such a time it goes, you know, further on up.

And at one point, there was discussion that our internal audit would put them under what one would call receivership. In other words, the department wasn't able to do the level of financial management that we expected for grants. It never got to that stage, but I think, you know, you really do have to do a communication and education process in order to get people to understand what their role is in compliance.

GEOFF GRANT: Good. Okay, then. Well, Nancy, if there's nothing else, I'll just say in closing that there is a bibliography of articles and resources in the back of the HHS publication. There's one in particular there, Grading Effective Compliance Programs in Academic Medical Centers. I understand it's an outstanding article. And even though it published in 1999, it's enduring and timeless even today, so I recommend it to your attention. And it's a pleasure to be with you all this morning. Thank you.

NANCY WRAY: Thank you, Geoff. We have, as you see, collected the comments. We will try to put something together and respond on behalf of the FDP. If, I hope you've had an opportunity to sort of review your comments, but, again, I strongly encourage you to respond to this initiative. With that, we'll adjourn. We will see you in May in Seattle. Thank you very much.