NATIONAL INSTITUTES OF HEALTH

STAKEHOLDER ENGAGEMENT WORKSHOP ON THE

USG POLICY FOR INSTITUTIONAL OVERSIGHT OF

LIFE SCIENCES DUAL USE RESEARCH OF CONCERN

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P R O C E E D I N G S

MS. WOLINETZ: Silence falls over the crowd. Welcome, everybody. I am Carrie Wolinetz. I'm the Associate Director for Science Policy here at NIH and I want to welcome everyone who is in the room, our research stakeholders, our federal partners, and all of you who are watching on the webcast today.

Welcome to our Stakeholder Engagement Workshop on The US Policy on Dual Use Research Of Concern. So, just to kick things off, we're going to dive right into it. I'm suspecting if you're here in the room at this meeting or if you're watching on the webcast, odds are good you're somewhat familiar with the dual use dilemma, the idea that good and beneficial science, technology, and research could potentially be misused for nefarious or non-benevolent purposes and it presents a really interesting sort of intellectual and practical dilemma. How do you facilitate what at the end of the day are really beneficial valuable lifesaving benefits of biological

research while still mitigating the potential risks of misuse.

And the flipside of that, of course, is how do you mitigate the potential risks of misuse without inhibiting the beneficial and valuable lifesaving benefits of biological research. And that is really what's bringing us here today. And I think it always important to recognize that although I think dual use research of concern and the whole sort of dual use arena is sometimes presented as sort of attention between those favoring science versus favoring security. The truth is I think there are a lot of common grounds. I think there is a broad general agreement that life science research is important, it has great benefits for human heath, for animal health, agriculture, the economy, manufacturing, sort of a broad range of sectors but I think there are also broad agreements that research and research results in the life sciences need to be conducted and communicated responsibly. This is something we certainly feel strongly about at NIH

and this is true not only of dual use research but on any number of issues related to the conduct of life science research when it comes to human subjects protection, the protection of animal subjects, the conduct of research in a responsible manner that involved in plagiarism or fabrication or falsification. It's important that we really support good and sound and responsible science, and it's really these two principles that are the foundation of a dual use research policy and any number of life sciences policies. And it's really a matter of finding the balance between the benefits and potential risks of the research.

So, what brings us together today? We are here to hear from all of you about the current Dual Use Research of Concern proposed policy for institutions, the IDURC policy. It seems like a timely place to hear from our stakeholders as the policy will be going into effect in September. So we're really interested in hearing your thoughts on dual use research of concern generally and to the IDURC policy specifically.

I just wanted to spend a moment NIH's role in DURC policy. NIH, the Office of Science Policy is involved in the management of the National Science Advisory Board of Biosecurity. We have a number of NSABB members here today so welcome to you all of you. And this is the group that has the role of advising the U.S. Government on issues related to dual use research and other biosecurity issues. The NSABB produces a number of reports and recommendations and those recommendations feed into the broader policy process of the U.S. Governments and that's an interagency process. A lot of federal agencies have a stake in this arena of research and are actively involved in the discussions and policy development going forward. And a number of those agencies are represented here today so welcome to all of you so welcome to all of you.

And, of course, I want to emphasize that the dual use research of concern policy, although it tends to be associated with NIH because we've got a large portfolio of research in this arena,

it's actually a U.S. Government policy and the next speaker will be talking a lot about the policy itself and its development and some current status.

So just to give you an overview of what we are going to talk about today, we're going to hear, as I just mentioned, from the White House Office of Science and Technology Policy about the current DURC policy landscape. We're going to talk with a number of experts about their experience, their practical experience in implementing the IDURC policy. We're going to go through an interactive case study -- we're going to make sure that you're all awake and are paying attention -- related to the IDURC policy, ad we're going to talk a little bit more about our outreach and education efforts relative to this policy. There's also going to be ample opportunities to talk amongst yourself because we're all here to learn from each other and we want to make sure that during the breaks and lunch, you get to talk to each other and network and learn from each

other.

So I also want to emphasize that we really do want to hear from you, from the research community. You are really where the rubber meets the road when it comes to the actual implementation of the policy. From my point of view sort of writ large, the more feedback we get from stakeholders, the better the policy that we ultimately develop and this is true on all sorts of fronts. And when it comes to implementation, you're really the experts. We need to hear what are your experiences, what are your concerns, what are the positive things that you're hearing from -- and this workshop today is not your only bite at the apple in that regard. We are happy to hear from you at any time. You can send email to DURC at OSTP.gov at any time over the course of -- well, frankly, any time.

And I did want to remind everyone -- I mentioned this in the beginning -- that this meeting today is being webcast -- so hello to all of you out there listening -- and that it will be

archived so, you know, if today was not enough, you can go back and watch it over and over again at your leisure.

And I just want to conclude by saying thank you for coming and it's really time for all of us to listen to what our experts and all of you have to say.

So without further ado, I would like to introduce Susan Monarez from the Office of Science and Technology Policy at the White House who is going to be walking us through some of the details of the DURC policy and how we got here. So Susan, please.

MS. COLLER-MONAREZ: Thanks, Carrie. Can you all hear me? I want to thank Carrie for really laying out the landscape of what we have to do today. And before we go further, though, there are two people that we definitely need to thank for even making this happen. First, I want to thank Ryan Bayha from NIH and Janelle Hurwitz from HHS who have been instrumental in formulating what we'll be talking about, making sure that we have

the appropriate panelists and running all the logistics that actually allow us to be here today. So Janelle and Ryan, thank you both very much for everything you've done to get us in the room.

I also want to thank the government panelists -- or the government representatives who are here today as well as the government moderators who will be walking through each one of the panelists. There is a, as Carrie mentioned, a wealth of expertise within the government, not just at NIH but across all government agencies that have an opportunity to help support life sciences research. We meet on a very regularly basis to ensure that we have consistency and a harmonized process for how we are understanding the dual use research of concern policies, how we're implementing them and how we're going to be transparent in working with all of you to ensure that we are working together as a life sciences community to develop the mesh work to reduce the risk that is posed by dual use research of concern.

I also wanted to welcome our international colleagues. We have a delegation from France who is here. We have had the opportunity from the White House and NIH as well to work with them over the past few years on what they are doing in this space, and we had an opportunity last summer to spend some time with representatives from the French government, and they have likewise started developing a framework to help understand the risks posed by dual use research of concern but also how to mitigate it. And they are not alone. This is an international dialogue that needs to take place. Our colleagues from the State Department are helping to facilitate that as well. And so we need to ensure that we're integrating and fostering the relationships on an international level to make sure that anything that we are working on productively here in the United States can be translated to the rest of our global partners.

I also want to welcome industry. There was a time where the government, the federal

government or state and local governments were the -- supported the preponderance of life sciences research. I -- what I see as a very exciting development is recently, we are seeing more and more private industry that is stepping up and playing a role in all of the good that comes from life sciences research. Ad so for those who are in the industry area, we welcome you to help join the conversation in understanding the nature of the risk posed by doing this research and how we can work with you to help mitigate that risk.

And then finally academia, so by-and-large, academia represents one of the largest sectors of life sciences research, and so making sure that we have a robust and consistent dialogue with you as you go to implement this particular policy as well as other policies in this area, we understand what's working, how it's working, what's not working and how we can do it better. And so as Carrier had said, we look forward to your feedback as well and we welcome your participation today.

Life sciences research is critical. Make no mistake. This is not something that a fear factor should be put in place and we don't do it. We must continue to support everything good that comes out of the life sciences research, the biomedical and public health advances, improvements in agriculture, safety, quality of our food supply, environmental quality and, of course, strong national security and economy. We need to make sure that we have a robust pipeline everywhere from the basic research elements through advance research development and fielding of technologies and tools.

And so one consistent theme that we have to make sure is as prominent in the dialogue as the risks are the benefits. So as we go through today, what I'm hoping that we hear part of the dialogue is how do we make sure that we're balancing that equation.

So just some definitions so that we have a common lexicon to go through the rest of the day. So the dual use research is essentially the

research that's conducted for legitimate purposes that generates the knowledge, information, technologies, or products that can be utilized for both the positive, the benevolent, as well as potentially harmful purposes. Dual use research concern is largely that same research but that can be directly misapplied to pose a significant threat with broad potential consequences to public health and safety. And it's that specific sector of that definition, "that could be directly misapplied," is where one where we need to maintain a dialogue.

There is, as there has always been, an evolution in the way that life sciences are conducted, the way that knowledge is gathered, the way that it's applied, and so a definition of "direct application," "misapplication for a harmful outcomes" in 1980 would not stand in 2015. We have to make sure that there is an integrated approach both in the life sciences as well as the security sector so that we know what could be exploited for negative purposes and how we might

put in policies or guidance to mitigate that. And so that critical "directly misapplied for significant threat to public health and safety" is one that we have to use as a filter as we're evaluating the dual use research.

So there have been over the past decade or so incidents where we can directly look at a set of experiments or the development of a knowledge product and point to it and say, "You know what, that probably was dual use research of concern." In 2001, the very classic and the one experiment that's often held up as sort of kicking this dual use research of concern genre was the Australian lab that introduced the IL4 gene into the ectromelia virus to produce what was the positive benefit which is the contraceptive vaccine to control the wild mouse population. What became interesting is that that modified virus then was more potent, more virulent than the wild type in naive mice and was able to overcome existing immunity in the mouse population. And s when you had the combination of a transmissible

virus in combination with an immunomodulator, it raised some concerns if that was the outcome in that particular scientific setting; how could it be extrapolated, and there was, of course, robust dialogue within the government.

In 2002, the Polio genome was reassembled from oligonucleotides. So being able to construct de novo a pathogen with human health implications not from an actual virus that was taken from a patient but actually constructed purely in the laboratory was the identification of, you know, reconstructing from sequence information alone of a particular or a potential pathogen.

In 2005, there was the reconstruction of the 1918 pandemic influenza virus. In 2005, there was also the description of modeling for vulnerabilities if the supply chain of milk was contaminated with botulinum toxin. So here we had an example of not actually the production of a pathogen that had the potential to cause harm but the knowledge and the understanding of where

vulnerabilities lied in our food supply chain and the potential significant outcomes that would happen if someone were to adulterate the food in such a way. And so it expanded our understanding of dual use research of concern beyond just bench scientists but also those who are thinking about broader applications of, you know, using biology to cause harm.

And then in 2011, many people in the room, you know, this was the first opportunity directly within government to think about, you know, the transmissibility of a pathogen between animal models where we had two labs demonstrating H5N1 avian influenza and there was very robust dialogue that took place within the NSABB which is, as Carrie mentioned, such a critical component of how the government thinks about dual use research of concern and all of the deliberation and the dialogue that went on both in the Fall of 2011 -- with discussion of the implications of that type of research, both from the development of a pathogen standpoint but also what is the

knowledge gained regarding virulence aspects of those pathogens, transmissibility aspects of those pathogens that could be then recapitulated by someone whose intention was not to enhance public health and safety but rather to exploit vulnerabilities. And then that directly led in 2012 to the development of which the dual use research of concern policy for the federal government often referred to as the March 29th, 2012 policy.

And then most recently, this past summer, there were a series of incidents that involved the discovery of vials of smallpox and then, you know, the bacillus anthracis most recently that had not been fully inactivated before shipment but also that was potentially held in a place that did not have the qualifying security measures in place. There was also the contamination of a non-pathogenic avian influenza with a pathogenic avian influenza, and then transmittal of an Ebola virus from a high containment laboratory to a lower containment

setting that also had not been inactivated.

And so all together, we have a series of events that continue to bring to life the need to make sure that we have robust policies in place to reduce the concerns posed by these pathogens and the research that is conducted on them as well as the knowledge of how they might be exploited.

Okay. So as Carrie had mentioned, the goal of the dual use research of concern policies that are in place and any that are developed for the gain of function component as well is it preserve the benefits of the life sciences research while minimizing the risk of the misuse of the knowledge, information, products, or technologies provided by such research. And we have to make sure that the policies that are put in place such as the federal policy for dual use research, the institutional policy, or any gain of function policy that's developed after this complement the existing regulations and policies governing the safe and secure use of pathogens without adding to the redundancy or the confusion

or any of the negative aspects of the policies that could be put in place.

So the two figures that I have at the bottom of this slide are -- the first one is a reminder, right; the coffee cup scenario. So had there not been instances when there dual use research of concern had risen to our awareness, we wouldn't need to develop these policies, but there are -- there have been in the past and there will be in the future. And so we need to make sure that we are working together to develop appropriate policies to mitigate the risks.

On the other hand, we have to make sure that there is a balanced approach to developing and implementing these policies, which is why it's so critical that you are here in the audience toady and at home on the West Coast, hopefully in bunny slippers and drinking your coffee, but, you know, the balance is between doing nothing, sort of the Wild Wild West approach where we anticipate that 99.9 percent of the research and the researchers that ware working in this space are

doing it for the appropriate reasons.

But there is that potential that, you know, things could go wrong one way or another. And so we need to put polices in place but we have to -- we can't overreact; right? So that's the other side of the equation is sort of the "Chicken Little" approach where, you know, we halt the productive science that will be done and put in place because of, you know, an overabundance of caution, recognizing that we are working with the most potentially dangerous pathogens on earth, but the productive life sciences that are stemming from this research need to be maintained for all their productive purposes. And so that is the goal and that is the challenge that the government faces in developing these policies. And so this, hopefully, is not the only time where we'll have this dialogue and we'll have an opportunity to have a discussion to integrate the public input into the policies as they are both being implemented as well as being developed.

Okay. So that's the general backdrop

and I just want to go over the Institutional DURC policy doesn't operate in a vacuum. There are other policies that are in place. There's an HHS framework for highly pathogenic avian influenza. As I mentioned, there was the 2012 policy which looks inwardly towards the federal government and how we provide oversight for life sciences dual use research. There is the Institutional oversight that is the subject of discussion today and then as many, if not all, of you are aware, there is there also the ongoing dialogue about a productive gain of function policy that is being led both with the National Science Advisory Board for Biosecurity in conjunction with the National Academies of Science with input from the government as well as public stakeholder. So that's the suite of policies that will be put in place or are in place to help shepherd production research while reducing the risk.

So in terms of this particular policy, it does leverage what was done in March of 2012 in terms of the same number of pathogens, the

pathogens that were identified back in 2012 as posing the most critical risk where they're essentially the tie one select agent pathogens. I won't go through each one of them. You can find your pathogen of interest. It's up here. But they were put there because they were identified at the time as posing the most existential risk in terms of dual use research. We know that they can cause harm to human health or animal health, and we know that manipulation of them I a variety of different ways could, you know, either develop a pathogen that has enhanced characteristics leaving us more vulnerable to the health impacts, or the research could be exploited, the knowledge of the research could be exploited to directly be used for nefarious purposes.

The seven experimental effects, again, I think we're fairly comfortable. These have been around essentially since the Fink Report looking at what types of experiments do we find may enhance the characteristics or alter the characteristics of a pathogen to cause harm. They

are consistently represented in the Institutional DURC policy. It's important that -- perhaps this will come up over the course of the dialogue -- is that there is a subjectivity associated with interpretation these seven experimental effects. It's something that we have talked about internally, so the government, I imagine, it's something that has been discussed in your institutions as you've been working through how to implement this policy. And so that's an area where we need to continue to have a dialogue, that the 15 pathogens that are static, I mean we all recognize what those are. But in terms of the experimental effects and the potential exploitation or how they are conducted, that evolves as technology evolves and our understanding of how things could be developed in a lab evolve as well. And so this is an area as we move forward on this policy or any gain of function that needs to remain flexible to accommodate changes in our -- in the risk environment.

So in terms of practical application of putting this policy in place, if an institution is working on one of those 15 pathogens and there is a potential that they're using one of the seven experimental effects, they're conducting research that would have one of the seven experimental effects, that would be consistent with how we would term dual use research of concern.

But there is that third sort of leg of the stool that we talked about earlier which is does it present to reasonably anticipate it provide information or a product that could be directly misapplied. And that's where a robust dialogue with those who understand the research needs to take place. It's not just enough to meet the first two criteria. It has to meet this third criteria which is direct misapplication to cause harm. And so we need to make sure we're having a consistent discussion amongst federal partners, institutions, academia, private sector, and also with our international partners to understand what is direct misapplication and how do we ensure that

we have a consistent application of the first of those three criteria, the 15 pathogens, the seven experiments of concern, and then this interpretation of direct misapplication so that we're all moving forward together in how we're applying this policy.

So if there is the sort of research that's being done in an institution that meets the criteria, those three criteria, there is a requirement to develop the risk assessment-risk mitigation strategies or do risk assessment and develop a risk mitigation strategy. And you're going to hear an entire section on this so I won't spend a great deal of time now other than to say that this is a very critical component. This is how we can make sure that that type of research can go forward and have some sense that the appropriate measures are being put in place at every level of an institution and within the federal government to mitigate the risk posed by that research. And then there's a variety of ways that one can develop a risk mitigation plan and

they're reflected here but you'll hear much more about them in this particular section during the workshop.

This is an area where I have heard now since the publication of the policy last fall a great deal of concern. How do we know which of these risk mitigation strategies are most appropriate for the type of research that we're doing? How do we know that the risk mitigation strategy that we are pulling together is going to meet the expectations of the federal funding agency? These are great questions and these are questions as you are -- as the research in your institutions is moving forward and your questions come up, this is why we have to have an open dialogue. This is why there is that durc@osep.eop.gov and that is why so many of your federal funding authorities are in the room today or watching this webcast, because our responsibility is to help you develop appropriate risk mitigation strategies, make sure that that research is going forward but that we are putting

together appropriate and substantive risk mitigation strategies to reduce the concerns about the research.

So there is something for everyone in this policy. There are responsibilities at all levels of the institutions so again, I'll just highlight these at sort of a generic level. You can read these and I expect these slides will be made available. I should also say that there is a set of training that NIH has developed that's on that -- the HHS S3 website which you can also look at the key responsibilities of the institutional and other officials.

But basically, when we designed this policy, we wanted to make sure that there was a meshwork in place at all levels of institutions and in any engagement with the federal government so that we had a full understanding at each institution that it wasn't just a PI's responsibility it wasn't just the bench scientists, it wasn't' just the institutional responsible official, it was everyone working

together in that institution to build out the appropriate understanding of what dual use research of concern is and how to mitigate it when it's seen.

So there are two key responsibilities for the institutions. The first is establish and implement policies and practices for identification, oversight of dual use research of concern and that includes all of the bulleted items that you see listed below.

And the second thing is an institution is required, if there is an identification of DURC that's ongoing, to notify the government funding agencies so it's to make sure that there is dialogue between the institution, they're aware of what's going on, they're aware of who's working on what. And if there is an identification that we do, in fact, have some DURC, that should in no way be -- working on DURC should not be a pejorative. It should not be something that oh, you know, doctor so-and-so's lab is working on DURC.

not at all.

What it is -- what it means is that it just needs to have situational awareness that this particular set of experiments, this type of research is in that sensitive category and so the institution is encouraged and obligated to make sure that they're contacting the federal government for and understanding that that's ongoing.

The key responsibilities for the investigator, so a down one level from sort of at that higher sort of administrative level, is to make sure that in the lab that you are overseeing, the work that's being done on your behalf with the federal funding, with the grant money, you know what the students and the lab techs and the post docs are doing in the lab, so working with them to identify and refer all of the dual use research to the institutional officials, working with the institutional officials to make sure that they understand what technically is going on, what are the risks, what are the benefits and be able to help support the development of the risk

mitigation plan from a technically defensible standpoint.

It's also a key aspect of the investigators is to make sure that there is an understanding by lab members what dual use really is. Having been in the lab for several years as an undergrad or grad student post doc, I'm not sure that I was always in touch with the Federal Register. As a matter of fact, I can say I never read the Federal Register. I think that making sure that as a PI, you have situational awareness of what the federal government is doing and communicating that to the entirety of your lab so that they have -- they're sensitized to the work that they're doing.

And then there's also a need to communicate dual use research of concern in a responsible manner throughout the research process and not just at the point of publication. This is also an area that we need to have additional dialogue. We certainly don't want institutions, PIs to start censoring themselves, to be in a

vacuum without a dialogue with their institutions, without their federal funding partners, to start thinking you know, boy, I shouldn't publish this sequence, I shouldn't talk about this (inaudible), those sorts of things. That may be appropriate. That may be something that you need to talk about with your institution or with your federal funding partners but we shouldn't have any sort overreaction in terms of undermining what's so critical and what's so great about how we conduct life sciences research here in the United States, which is we have open data requirements. We -- you know, if you publish something in a journal, you make available the information so that somebody else can do similar type of experiments. That's the whole basis of peer review is to be able to do that type of work. And so we need to figure out the balance between putting out information that can be directly misapplied with what we need to make sure is going on in science so that we have the best science conducted to enhance, of course, public safety and health.

Okay. So there are some very technical areas about the IREs. You know, they have to have at least five members. We would hope they have knowledge of why it is that they're meeting the government policy, and they have to have a bronze rate of expertise. I know that, you know, in administrative levels within certain settings, there are various ways that that type of a committee can be made, but it's so critical that you have scientists as part of the review committee that understand the science, that can appropriately weigh the risks and the benefits and aren't entirely reliant on one voice or another to be able to make that decision. So it's absolutely critical that scientists are supporting the IREs in the institutional review.

The IREs are ultimately going to be responsible for verification of the research. You know, the 15 agents is sort of the easiest part; the 7 experimental effects is the more subjective part and then the most subjective part is the determining whether or not something is DURC. And

then if it is determined to be DURC, why it's so critical to make sure scientists are part of the IRE is that you have to conduct the risks and benefits. Once all of the sort of the intellectual components of the evaluation of dual use research of concern are completed, the more formulae is to develop or to work with the federal funding agencies to work with a risk mitigation plan and then certainly once a DURC is identified, the risk mitigation plan is put in place. There needs to be ongoing evaluation. Things change in a lab. Everyone who's ever tried to make a construct and put it in a pathogen and see what happens knows that research goes in all sorts of directions. It could end up being completely non-pathogenic. It's not DURC and that can be explained to those who need to continue evaluating for DURC. It can go an entirely different way and it can go much more like the ectromelia IL4 research. There just has to be a consistent dialogue to ensure that nothing is slipping through the cracks one way or another.

It's, as I think many of you have pointed out, who is going to be coordinating with the federal government, who is going to make sure that there is a consultive process that happens between the institution and the government as well as, you know, within the institution and that's the responsibility of the institutional contact for dual use research. And so this person needs to have an operating knowledge of the funding agency, the policies in place, and they really need to make sure that they are active in that dialogue between the institutions and the government, and they are such a critical component to implementing this policy that considerable thought needs to be given to who ought to be put in that position.

So the federal government also does not get off easily. There are responsibilities of the government funding agencies. We -- the federal government funding agencies -- and as I said, you know, there are tireless workers within the federal government and that's one thing that just institutions, if you take nothing else away from

this dialogue, know that you have, depending on who your funding, what area you work on, you have someone on the other end who is thinking very hard about how to maximize utility of this policy, what's working, what's not working. And the federal government does require policy implementation at all institutions that are subject to this policy.

When the federal funding point of contact is notified by an institution that research is meeting the scope of the policy, they need to notify the institution of the U.S. government agency if it disagrees with any part of the IRE's review outcome. So that's an opportunity for the institutional review entity to articulate to the federal government here is why we think this is DURC or not DURC, here's the risk mitigation plan we put in, here's how we think that it solves the problem. That's going to be an ongoing dialogue and it should be anticipated that there is a very robust dialogue.

As I said, this is a meshwork. We are

all in this together and so we have to make sure that there isn't -- there's no complacency. We challenge ourselves, make sure we're doing everything that's in the best interest of the public for this type of research, and so we have that discretion about, you know, have we looked at every aspect of the research, have we looked at every aspect of the risk mitigation strategy, and are we doing the best to make sure that we haven't missed anything.

And then we're also, the federal government, as I said, is required to respond to the questions from the institution regarding the DURC oversight and compliance with the policy. That's our job. So we put the policy in place. Our obligation to you is to make sure that you understand it, that you know how to implement it, and if there are any questions, concerns, or comments, that we can address them. And so that is why we're here today and that's why we have that email address where you have the opportunity to engage. And you should also, as institutions,

get to know your funding agencies and the point of contacts there so you can have that ongoing dialogue.

So as I mentioned, there is that email address. It is staffed. It's not an email address to nowhere. I actually have it. It comes to my desk and it comes to others as well, so I do monitor that to just get a sense for how the questions that are ongoing about implementations of this policy -- and then where there are significant issues that potentially need White House attention to make sure that I have full situational awareness of what's going on.

There is also a wealth of materials which is at the S3 website. I highly, highly encourage as you are working on implementing this institutional policy go to the website, look at the case studies. We'll hear one today. There are more on the website. Look at the training slides. Training is a required element of this policy. There are a set of training slides that have been developed by NIH.

And then if I can just close by one last thing is as I've said, this implementation of this policy, implementation of any follow-on policies for gain of function need to be in an open and transparent manner. We need to make sure that you understand what it is that we're thinking and why we're putting these policies in place. But we also need to understand how -- the challenges you're facing in implementing, whether it's confusion about the language, confusion about an action, confusion about decision-making, any of those sorts of things. Our job is to make sure that you can do your job and so please look at the materials on the S3 website, send your emails to durca@ospt.gov, and let's make sure that we have a productive set of policies in place that are doing exactly what it is that we hope to do, which is buying down the risks posed by dual use research of concern.

So I'm going to stop there. I will be here all day. I will also be here at the end where we'll have some additional dialogue and

identify any questions. Please feel free to reach out to me, reach out to your colleagues here as well, and we'll try to make this a highly productive discussion. So thank you very much for your attention and I will turn it over to Carrie.

(Applause.)

MS. WOLINETZ: Thank you so much, Susan, and I'm actually going to turn it directly over with no further ado to Marci Wright who is going to lead us thro ugh the case study.

MS. WRIGHT: Can you folks hear me? Let's see. Well, hopefully, that's better. That sounds good. Okay, perfect. Hi. Good morning. I'm Marci Wright. I'm with the U.S. Department of Health and Human Services Office of the Assistant Secretary for Preparedness and Response and would like to welcome you to today's discussion and it's so nice to see so many familiar f aces out there.

We -- I want to give folks who are joining us by webcast an opportunity to follow along with the case study. It will not, unfortunately, be an interactive session for the

case study but we still welcome your comments and your feedback. And as Susan mentioned, we encourage you to submit your comments on the case study at durc@ostp.gov. You can download the case study and the institutional DURC oversight policy at phe.gov/s3/durcworkshop. So I just want to give folks who are one to get those materials. Does everyone have a copy of the case study in your hand?

(No audible response.)

MS. WRIGHT: Okay, anyone not have it?

(No audible response.)

MS. WRIGHT: All right, great. I just want to provide a few little guidelines for today's discussion. This is the fun -- well, the rest of the day is the fun interactive portion and especially now, so we're really hoping for your frank comments, feedback on the case study. And I want to just throw out a few little guiding principles that we used in our partnership to develop the case study as well as how well managed going forward.

So when we developed this, we clearly developed something that was fictional and that had no representation of or connection to any individual, any institution, or any research protocol. Our guiding principles clearly are that we're all committed to supporting and promoting a collaborative, interactive and learning environment for this case study. Clearly, we want to illustrate the institutional DURC oversight policy process so that folks have a clear understanding of what requirements are from all entities and stakeholders involved in this effort and then broadly that we emphasize a culture of responsibility for DURC oversight and the responsible conduct and communication of research.

So our learning objectives today are two define dual use research of concern and then Susan has provided that definition. We'll return to that clearly in this case study to understand the scope of the institutional DURC oversight policy, and then to clarify the roles and responsibilities of the many stakeholders that have equities in

this process and t hose are listed here. We want to ensure that principle investigators, that institutions, that those who might populate or staff an institutional review entity or might staff the institutional contact for dual use research and then certainly, the U.S. Government, that we all are clear about what we are to do in how to apply this case study.

So in this case study, we are going to be using Francisella tularensis, a bacterial pathogen that's the causative agent for tularemia, a serious disease. We wanted to use tularensis as the model system for this case study for a couple of reasons. First, it is generally manipulated in biosafety level three conditions depending on biological risk assessment. It -- there are several subspecies and strains that are either subject to or exempt from the select agent regulations. And the goal of using this was to give us the most leverage and flexibility that we could to exercise multiple aspects of the case study.

We recognize that there are technical aspects to this case study that might not reflect the current up-to-date technical knowledge base. Please bear with us on that. However, if there are aspects that directly impact an understanding or interpretation of pieces of the policy, please do let's talk about those things.

So Susan's done an outstanding -- Susan and Carrie have done an outstanding job of framing the issues that the U.S. Government and that our external to government stakeholders are dealing with and grappling with as we apply this policy, and so I want to work very carefully to ensure that I have established a toggle or a primer, if you will, for the three criteria that we will be returning to during the exercise of this case study. And essentially, we're going to be asking does the research involve one of the 15 agents or toxins listed in the policy. We're going to ask will the research produce or aim to produce any of the seven experimental effects listed in the policy. And then finally, we will ask does the

research meet the definition of DURC as described in the policy.

All right. So with that said, let's go ahead and jump in. I should mention that this is supposed to be highly interactive so I will be asking questions to the large group. I will also ask you to consider chatting with your neighbors at times during the case study to talk amongst yourselves and sort of think through some of the questions that we might not have clear answers to during this case study. And Dana Perkins, thank you so much for agreeing to provide a mic for folks who might wish to respond.

So let's go ahead and jump in. Part one, so we are introduced to Dr. Jameson, a tularemia expert w ho has just joined Boyle University. Dr. Jameson is interested in how Francisella tularensis infects a million cell lines, and he's specifically interested in the role of type 3 secretory system pathways. And so he wants to characterize the type 3 secretory system pathway using Francisella tularensis

subspecies novicida. And he's going to do this through modifying T3SS effector genes.

He seeks and gets IBC approval from Ms Locke, his institutional biosafety officer, and she reviews the protocol. The IBC reviews the protocol. They consult with the Office of Biotechnology Activities at NIH and approve the work to be done in biosafety level two conditions. So first question that we're asked is, is this experiment subject to the policy and folks can just call out an answer.

PUBLIC SPEAKER: (Inaudible.)

MS. WRIGHT: So we have a yet and a no. Any firm yeses?

PUBLIC SPEAKER: (Inaudible.)

MS. WRIGHT: Any firm "nos"?

PUBLIC SPEAKER: I would say no.

MS. WRIGHT: So we have a no in the back?

PUBLIC SPEAKER: (Inaudible.)

MS. WRIGHT: Could you repeat that, Patricia?

PUBLIC SPEAKER: I would say no because it's an attenuated organism and on the select agent list.

MS. WRIGHT: So it's not on the select agent list. So we want to apply that first question that we ask; does the research involve one of the 15 agents or toxins listed in the policy and for the current federal select agent regulation policy, the Francisella subspecies novicida is exempt and excluded from select regulations.

Okay. All right. So moving to page three, Dr. Jameson, he's working with novicida but he decides that he would actually like to change species. He's going to move to subspecies tularensis tularensis. He's working with the strain SHUS4. This is a non- attenuated virulent strain. He still wants to characterize the type three secretory system pathway by modifying effector proteins in that pathway. He specifically communicates that he wants to disrupt these effector proteins. So he asked -- he

approaches this time the IBC Chair, Dr. Greenore, and asks how to get approval for the amended IBC registration.

So let's just take a few minutes just to read through that piece on page three. So we're posed with the same question. Is this experiment subject to the policy? Any yeses or nos? I heard a yes. Any nos?

PUBLIC SPEAKER: (Inaudible.)

MS. WRIGHT: No nos. And yes, so why?

PUBLIC SPEAKER: Now the virulent strain is on the select agent list.

MS. WRIGHT: So this is tularensis tularensis SHUS4. it does not have the CLP delta exclusion and therefore is subject to the select agent regulations. And Dr. Wyant's (ph) shaking his -- nodding his head I believe.

All right. Okay. So before we do this or before we move on, we should ask what additional information at this point should Dr. Greenore communicate to Dr. Jameson about how to proceed with this particular experiment? So Dr.

Jameson's gone to Dr. Greenore. He said, "Hey, I need to amend my IBC regulation or submit a new one to work with tularensis tularensis." Dr. Greenore is the chair of the IBC.

Is there any additional information that she can communicate to Dr. Jameson? Hint: why we're here today.

PUBLIC SPEAKER: (Inaudible.)

MS. WRIGHT: Sure. We're hoping -- so the reason that we selected having Dr. Jameson first approach the institutional biosafety officer and then approach the institutional biosafety committee chair is that in many governance structures, that first handshake, that first communication between the investigator and the oversight structure of the university occurs between the investigator and the BSO or the investigator and the IBC chair. So we are hoping that both o these individuals will have some knowledge of the institutional DURC oversight policy so that they can appropriately ferret and funnel people to the appropriate individuals.

So some of the additional information that Dr. Greenore might communicate would be to introduce the policy, introduce the ICDUR, and introduce the institutional review entity process.

Okay. All right. Moving on to page four. For this part, we do ask that you find a neighbor or a couple of neighbors and read through page four and consult with your neighbors to think about answering questions four through seven.

PUBLIC SPEAKER: (Inaudible.)

MS. WRIGHT: So that's a great question. Do you believe as the case study is written that Dr. Greenore had enough information to advise -- or that the IRE, if it were going to be convened to look at this, would have enough information?

PUBLIC SPEAKER: (Inaudible.)

MS. WRIGHT: No, we don't. For the --

PUBLIC SPEAKER: (Inaudible).

MS. WRIGHT: Okay. So the answer for the purposes of this case study and the experiment that we've -- that Dr. Jameson is proposing for experiment to, the answer is "no." He's actually

doing -- conducting a loss of function experiment, right, so he wants to disrupt the T3SS effector mechanism.

PUBLIC SPEAKER: 0:54:55(Inaudible.)

MS. WRIGHT: Sure, tell me more.

PUBLIC SPEAKER: (Inaudible.)

MS. WRIGHT: Right. And so I believe in the --

PUBLIC SPEAKER: (Inaudible.)

MS. WRIGHT: -- right. Okay. So Dr. Burns, can you repeat your question? It's a great question.

PUBLIC SPEAKER: Question is where are we with regard to the Biosecurity aspect since it's a select agent registration (inaudible) --

MS. WRIGHT: Absolutely. So we've got a little language in the case study that indicates that Dr. Jameson's research is registered with the select agent program. The facilities registered so he is up to date and free and clear to work with tularensis tularensis. A great question. Okay. All right. So let's move on.

PUBLIC SPEAKER: (Inaudible.)

MS. WRIGHT: That is correct. Thank you. Thank you, Rick. That is correct. Yeah. He would -- we're operating on the assumption that he's met all of the requirements with the select agent program here at Boyle University.

All right. So moving on, we are going to move on to page -- let's see where I am -- page four. All right. So here Dr. Greenore, having learned that Dr. Jameson wants to modify these effector proteins and he wants to use tularensis tularensis, tells Dr. Jameson that his experiment may be subject to this policy and that he needs to submit this proposal to the newly established institutional review entity. So this is the first time we're hearing about the IRE or the institutional review entity. So Dr. Jameson says, "Well, what is this about; what do you mean; what is DURC?" And Dr. Greenore begins to describe DURC. And Dr. Jameson says, "Well, you know, I really don't think that my research rises to the level of DURC so therefore why do I need to engage

the IRE?"

And so Dr. Greenore clarifies that not all research subject to the policy is DURC, so not all research conducted on one of those 15 agents is -- will be DURC but that research on any of those 15 agents listed still must be reviewed for the potential to be DURC. So as soon as the investigator has identified or disclosed that he or she is working on one of those 15, the IRE needs to be notified and the university needs to have a -- the institution needs to have a mechanism in place to engage the IRE.

So we're asked question number four. What methods can be used to socialize the policy to investigators so that they're clear on the process?

PUBLIC SPEAKER: Maybe some kind of mandatory online training similar to the trainings that investigators already get for if they're working with BSL2 agents, where they're going to be registered that they're in a certain lab or they're working with a certain thing and so

they'll be required to participate either one time or annually in some kind of online training.

MS. WRIGHT: Absolutely. Thank you. Any other comments? We have -- I think we have a comment in the back.

PUBLIC SPEAKER: You could consider adding institutional controls like putting in some lines about DURC in their IBC applications as well as when they're processed -- when their grants are being processed through the university system, some components in there to make them address the issue at an early stage.

MS. WRIGHT: For -- this is a little bit easy because we're dealing with agents that are already on the select agent list so we would expect that the responsible official and the select agent program at an institution is going to be very clear who is working with what, when, and assist with making sure that that communication occurs and that the training is being conducted to ensure that the PI is aware of what his or her responsibilities are under the policy.

So Dr. Jameson still clearly has some questions, so Dr. Greenore says, you know, you really need to talk to the ICDUR, so that beloved term, -- institutional contact for dual use research. And so Dr. Jameson says okay and then Dr. Jameson begins to engage Mr. Midleton who is the Senior Vice President for Research at the institution and who functions as the ICDUR.

So who could function in this role at an institution?

PUBLIC SPEAKER: (Inaudible.)

MS. WRIGHT: So I heard responsible official.

PUBLIC SPEAKER: I was going to see either a select agent responsible official or perhaps vice president of research at the institution.

MS. WRIGHT: What is the role of the ICDUR. Jumping ahead a little bit but what is the role of the ICDUR according to the policy; what does the ICDUR do?

The ICDUR is the -- go ahead.

PUBLIC SPEAKER: (Inaudible).

MS. WRIGHT: Right. The ICDUR, the primary responsibility is that is the individual who is going to communicate with the funding agency on the outcome of the IRE's deliberation, on whether a particular proposal rises to the level of DURC, on the development and submission of a risk mitigation plan and then going forward, sequelae from that. So the ICDUR is that institutional contact who will communicate with the funding agency.

So moving on to page five, let's -- again, we're going to ask you to consult with your neighbors to talk a little bit about this. I'm skipping over questions five and six. We're going to get back to training a little bit later on in the case study. So Dr. Jameson talks with the ICDUR on page five, Mr. Midleton. Mr. Midleton discusses the policy, discusses how the Boyle University will implement the policy, and discusses the role of the institutional review entity. Mr. Midleton also provides Dr. Jameson

with a little information on who staffed the IRE, and so I believe we have a neurologist, we have Dr. Greenore, a bacteriologist; we have another microbiologist; and I believe we have the BSO.

So let's read a little bit about that conversation. How would you constitute your institutional review entity? What subject matter expertise do you believe is best served by being staffed on the institutional review entity?

PUBLIC SPEAKER: So first of all, you'd need subject matter experts, right, so faculty members who could do the risk assessment appropriately. We include someone from research administration, so the director of research administration is on our board and we have an attorney on our board. So that's what we've done.

MS. WRIGHT: So senior research administration, scientists, faculty members, counsel, and risk -- probably a risk management team from the university/counsel. Any other expertise?

PUBLIC SPEAKER: Folks from compliance

may actually want to incorporate the IRB's ethicist.

MS. WRIGHT: Okay, great. Any other?

PUBLIC SPEAKER: We have folks from scientific editing and communication in there because at some point, this information will have to be released in a publication. So we get these people involved very early on to make sure that the way this information is disseminated is done in a manner that's appropriate.

MS. WRIGHT: That's great. So your communications/public affairs. That's outstanding. Any others? I can think of maybe one more set of folks I'd like to see. Sherry (ph).

PUBLIC SPEAKER: (Inaudible.)

MS. WRIGHT: IACUC representative, so you're Institutional Animal Care and Use Committee. Any others?

PUBLIC SPEAKER: (Inaudible)

MS. WRIGHT: Department of Public Safety, yeah, you're getting into your true safety and security folks, police, law enforcement.

PUBLIC SPEAKER: (Inaudible.)

MS. WRIGHT: Right. So I want to raise one thing during this discussion. So Dr. Jameson has gone from one extreme saying, you know, I don't think my research constitutes DURC so I don't need to talk to the IRE. And then having talked to Mr. Midleton, he says, oh, gosh, I am using one of these agents, one of the 15 agents; therefore, my research is DURC and I must now submit a risk mitigation plan. Is Dr. Jameson's understanding of the policy and they process correct? Is his research DURC and must he submit a risk mitigation plan with what we know? Dr. Ellis says no.

PUBLIC SPEAKER: (Inaudible.)

MS. WRIGHT: Not until we check out whether the research aims to produce one of the seven experimental effects listed in the policy. Any other comments on what we've covered so far for Dr. Jameson and his project?

(No response.)

MS. WRIGHT: All right. So let's go

ahead, move on to question -- to page number six. Okay. So we're going to get into this. I jumped the gun a little bit but we're going to talk about the seven experimental effects. So Mr. Midleton says, "No, Dr. Jameson, your understanding is not correct. Yes, you are working with one of the 15 listed agents but there are a couple of steps that we have to evaluate within the IRE before the determination is made that the experiment is DURC and that a risk mitigation plan is required."

So reading page six, the IRE, we're told, conducts the review of Dr. Jameson's proposed research with a T3SS disruption and they determine -- they make two determinations. Clearly, the research is within the scope of the policy. They determine, based on this case study, that the research will not produce any of the seven experimental effects listed in the policy. So, therefore, the IRE concludes that the research is not DURC. So Dr. Jameson's experiment has met criterion one, it has not met criterion two. Therefore, it does not rise to the level of DURC

as described in this policy.

Okay. All right. I think we've covered that. Okay. However, the IRE does say one thing. They say, Dr. Jameson, if your research aims change at all in any way, let us know, right. So we know that happens between our annual reviews, our annual CRISPR project reports within, the NIHR annual progress reports there is a lot that can change, and the IRE needs to be kept apprised of any particular changes to this protocol. And so institutions are encouraged to think about what that closed feedback loop would look like for them as they adjudicate IRE decisions that do not require a risk mitigation plan. So they still want to have that relationship and ongoing dialogue with the investigator.

All right. So moving on, we're going to move on to page seven. So, okay, so Dr. Jameson's doing great. He's got a new grant. He's doing well. He's, you know, exhausted his work on type three secretory systems and now he's actually interested in what's happening surface proteins on

Francisella tularensis tularensis. So he's still working with tularensis subspecies strain SHUS4 and this time he's interested in modifying a surface antigen and modifying the antigenicity of tularensis by modifying this particular surface protein. So he hypothesizes that this modifications will enhance the ability to tularensis to survive and replicate in cells.

So I want to give folks just a minute to just read this particular experimental design on page seven. I'm sorry, Sarah, missing? Got it. Okay, great. Thank you. Okay. So on page seven, he hypothesized that this modification is going to enhance the ability of Francisella tularensis to survive and replicate in infected cells. What is the clinical significance of this experiment? Why might this get a little bit of attention? So if you're modifying the antigenicity of tularensis by changing a surface protein, what might you think about from a clinical disease infection control perspective?

PUBLIC SPEAKER: (Inaudible.)

MS. WRIGHT: Okay. So are you changing the effectiveness of your medical countermeasures or vaccines? Are you changing the tropism of this bacterial pathogen? Any other clinical considerations?

PUBLIC SPEAKER: (Inaudible.)

MS. WRIGHT: Sorry, go ahead.

PUBLIC SPEAKER: (Inaudible.)

MS. WRIGHT: Okay. So because you are enhancing replication, you're then thereby increasing the infective dose inside the host. Okay. And Dr. Burns.

PUBLIC SPEAKER: The question of evading the host immunity, that's the key issue.

MS. WRIGHT: And that -- right. And so that's the key answer for this particular case study. The other answers are valid and should be considered but for this case study, yes. So this, Dr. Jameson is now proposing to develop a strain of tularensis that might evade host immunity. Okay. So that might get someone's attention.

Okay. So since Dr. Jameson plans a

modification of his experimental aim with the existing research plan, when is the most appropriate time for him to consult the institutional review entity? Do you think this rises to a level of a phone call to say, hey, you know, I want to do something a little bit different here?

PUBLIC SPEAKER: Yes, it does.

MS. WRIGHT: Yeah, absolutely; yes, resounding absolutely. And when should he do this? Should did he say, hey, you know, I started this last week, last month, six months ago?

PUBLIC SPEAKER: (Inaudible.)

MS. WRIGHT: No. He should get IRE review and approval before the work commences and so for those who are familiar with IBC processes, you know, the processes and checks might sound a little familiarbut we want the IRE to have input and to provide direction to the investigator before the work actually goes forward. Any comments or questions on that?

(No response.)

MS. WRIGHT: Okay. So moving on to page eight, we learn that the IRE decides correctly to review this particular proposal to modify the surface protein. And they want to review this in the context of the policy which says well, once you know that a listed agent is being manipulated, that it's subject to the policy, now we want o ask the second criterion. Does the research aim to produce any one or more of the experimental effects? So let's look carefully at the experimental details on pages seven and eight. Which, if any, of the seven listed experimental effects does the research aim to produce? And Susan has posted this earlier today. So we have a hint. Dr. Burns said, "Well, the big enchilada is that he's wanting to have this evade host immunity." Let's think about this. Any others? Rick Number one, enhance the harmful consequences of the agent or toxin. Any others?

Number two, disrupt the immunity or the effectiveness of an immunization against the agent or toxin without clinical and/or agricultural

justification, good. Anything else?

Someone said number six, enhances the susceptibility of a host population to the agent or toxin. Number three, confers to the agent or toxin resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions. Any others?

Number four, increases the stability, transmissibility, or ability to disseminate the agent or toxin. Any others?

Number five -- I feel like Bob Barker -- alters the host range or tropism of the agent or toxin. So as Susan said earlier today this is a subjective -- I mean this is an educated subjected evaluation and this is why you want a properly constituted IRE, right, with the appropriate subject matter expertise. And these are -- and as Susan mentioned, these are some of the discussions that we're having internally to the U.S. Government and that we hope to continue having with the community which will be applying this policy.

For the purposes of this case study, this IRE identified two experimental effects. So having identified these two experimental effects, what are the next steps for the IRE and for Dr. Jameson?

PUBLIC SPEAKER: (Inaudible)

MS. WRIGHT: Okay. So I heard develop a risk mitigation plan. Notify the funding source. Okay. Answer the question three, does it meet the definition of DURC. Okay. So develop a risk mitigation plan, notify the funding agency, determine whether the experiment meets DURC. That actually -- all three are correct. They happen in one specific order. What comes first?

PUBLIC SPEAKER: (Inaudible.)

MS. WRIGHT: I'm sorry?

PUBLIC SPEAKER: (Inaudible.)

MS. WRIGHT: No.

PUBLIC SPEAKER: (Inaudible.)

MS. WRIGHT: Notify the funding agency. Notify the funding agency. Notify the funding agency that there is a agent that's listed on list

of 15 in the policy, that the research aims to produce one or of the seven experiments of concern -- excuse me -- experimental effects, and then notify the funding agency of the outcome. And I apologize. I've mixed that up.

You do want to determine whether the experiment rises to the level of DURC, so I'm sorry. So DURC comes -- determination of DURC comes first. However, the point that I was trying to make is that the funding agency needs to know the outcome of the IRE deliberation, whether the IRE determines that it does meet DURC or that it doesn't meet DURC. Okay.

All right. So moving on to slide 14. We then have here the definition of DURC. I'll read that. Life sciences research that based on current understanding can reasonably be anticipated to provide knowledge, information, products, or technologies that could be, for emphasis, directly misapplied to pose a significant threat with broad potential consequences to public health and safety,

agricultural crops and other plants, animals, the environment, material, or national security. So this is the standard by which the IRE is going to determine whether the proposed project rises to the level of DURC.

And we have a comment in the back.

PUBLIC SPEAKER: I just have a question. Your comment on the previous slide, are you suggesting that they -- if the IRE determines it's not DURC, they still need to notify the institution? That was what I thought I heard.

MS. WRIGHT: That is correct. If the IRE says yes, this research involves one of the listed 15 agents; yes, this research aims to produce one or more of the seven experimental effects, at that point, the IRE is going to evaluate whether the research rises to the level of DURC. If the answer is "yes," the IRE, through the ICDUR, notifies the funding agency. If the answer is "no," the IRE, through the ICDUR, notifies the funding agency. Any comments? Okay.

And so for this experiment then, we note

that the research does involve one of the 15 agents, the research does produce, for this IRE's evaluation, two of the experimental effects, and the research meets the policy's definition of DURC. And the IRE determines that because the antigenic modification of this surface protein is going to enhance the ability of tularensis to survive and replicate in cells. They assess and determine that that poses a direct -- can be directly applied to pose a significant threat and broad potential consequence to public health. Rick?

PUBLIC SPEAKER: Marci --

MS. WRIGHT: Rick.

PUBLIC SPEAKER: I just kind of just want to ask the same question again because it kind of surprised me. That was -- if the IRE determines that it doesn't meet the definition of DURC, they still have to notify the funding agency?

MS. WRIGHT: That is correct.

PUBLIC SPEAKER: Thank you.

MS. WRIGHT: That is correct. Regardless of the outcome, the IRE must notify the funding agency. Comment?

PUBLIC SPEAKER: (Inaudible) previous comment, the why. I mean, to me, you're going to do that because the funding agency may assess it and disagree. Did they have -- do they have to agree with your determination of DURC?

MS. WRIGHT: So the question is why does the IRE need to notify the funding agency of its decisional outcome if the IRE determines that the research does not rise to the level of DURC; is that correct? That's your question?

PUBLIC SPEAKER: (Inaudible) wanted to say (inaudible) question

MS. WRIGHT: Okay. So you're saying that yes, the IRE needs to ensure that the funding agency concurs with the IRE's decision. Any comments from my federal partners? Yep, okay, go ahead.

PUBLIC SPEAKER: (Inaudible) this criteria, I'm going to pose the argument to number

(inaudible) necessity four, we decide if it meets the criteria of DURC.

MS. WRIGHT: So the risk and benefit analysis is going -- the risk assessment is going to come in advance of developing the risk mitigation plan.

PUBLIC SPEAKER: (Inaudible.)

MS. WRIGHT: Did you have a comment, Chris?

PUBLIC SPEAKER: No. (Inaudible.)

MS. WRIGHT: Okay.

PUBLIC SPEAKER: Well, I was going to say -- all right, my comment was that I think --

MS. WRIGHT: And yes, you would do a risk analysis of whether this research would directly -- could be directly misapplied to pose a significant threat to public health. So yes, there is a risk assessment component to that.

PUBLIC SPEAKER: I was just going to say an important element to the DURC policy is to open up a line of communication between the institution

and the federal funders. So that's the reason why it's important to contact the funding agency even if you only meet these first two steps, the 15 and the 7 because as we've talked about, the DURC definition is a bit subjective so it's' really nice to have a dialogue around that between your funder and the institution.

MS. WRIGHT: So we want to engage the funding agencies and have funding agency input on this particular subjective evaluation. Okay. All right.

Okay, moving on. I'm going to move on to -- let's see, where am I -- slide -- okay, so this is important. So now we just want to take a step back because we've had two -- three experiments evaluated. We want to ask what notifications are required to be made and when. Anyone want to take a stab at this?

PUBLIC SPEAKER: (Inaudible.)

MS. WRIGHT: So we've determined that the experiment engages one of the seven experimental effects, the IRE has determined that

for this case study, the experiment does meet the definition of DURC in the policy. What needs to be done next and when and how long?

PUBLIC SPEAKER: (Inaudible.)

MS. WRIGHT: Okay. Any other comments on how long to develop the draft risk mitigation plan? What about notifying the funding agency of the outcome of the IRE deliberations; how long for that?

PUBLIC SPEAKER: Thirty days.

MS. WRIGHT: Thirty days, okay. All right. So again, here are our criteria. If the research involves one of the 15 agents or toxins listed in the policy and the research produces any of the 7 experimental effects listed in the policy, the institution, through the ICDUR, must advise the funding agency of the outcome of the IRE's decision within 30 days of the IRE decision. And again, we've said whether the decision is that the research rises to the level of DURC or not.

PUBLIC SPEAKER: Going back to the bottom paragraph, you know, if the IRE determines

that it is not DURC, isn't the ball in the funding agency's court? If I was the funding agency, I would want to know why not. So essentially, the responsibility is being shifted. To me, it seems like it's mandatory if we are doing that that we send, you know, why it is not DURC because that's what's going to follow.

MS. WRIGHT: Any comments from my federal partners?

PUBLIC SPEAKER: (Inaudible.)

MS. WRIGHT: Right. So you're asking then is the funding agency ultimately the final arbiter on this decision?

PUBLIC SPEAKER: (Inaudible.)

MS. WRIGHT: If the first two are yes.

PUBLIC SPEAKER: (Inaudible.)

MS. WRIGHT: That's correct, yeah; yep. This was -- we have what we call a murder board process in our discussions and this was my big murder board question. Absolutely, thank you.

All right. How long after determining that a project constitutes DURC must a draft risk

mitigation plan be submitted to the funding agency? I believe we had an answer and what was that?

PUBLIC SPEAKER: (Inaudible.)

MS. WRIGHT: The draft plan must be submitted within 90 days of the IRE decision. Okay. We're going to talk about how long does the funding agency -- once this is submitted, how long does the funding agency have to provide a response and to provide a final approved risk mitigation plan. We'll circle back on that at the end of the session.

PUBLIC SPEAKER: So in all of these examples, you're saying the funding agency but on the page two, you say there are several agencies that are funding them. So one thing you don't know in here is which agency they're reporting all of this to.

MS. WRIGHT: No, that's a great question. So the question for folks on webcast is if this particular project is supported by more than one funding agency, which funding agency or

agencies would get the communication from the ICDUR on the outcome of IRE proceedings.

PUBLIC SPEAKER: (Inaudible.)

MS. WRIGHT: So I'm not a grants person. Is there a primary funding agency that would be the point of contact for a specific project or contract?

PUBLIC SPEAKER: (Inaudible.)

MS. WRIGHT: So the question is if a particular project, if a specific aim or a grant or a contract is -- has support from more than one or a project has support from more than one funding agency, which funding agency or agencies would the ICDUR then contact and apprise of the IRE deliberations.

PUBLIC SPEAKER: Yeah. I think there would have to be a communication to each of the federal funding agencies and then the funding agencies would have to coordinate --

MS. WRIGHT: Right.

PUBLIC SPEAKER: -- so that it wasn't a duplicative effort, so that it was a streamlined

approach.

MS. WRIGHT: So we'd work within the government to ensure that we are coordinated if that scenario happened. I'm not quite sure that that does happen on a particular notice of award. I think notices of awards come from one specific entity.

PUBLIC SPEAKER: Yeah. (Inaudible) example (inaudible).

MS. WRIGHT: Okay. So the ICDUR would talk to the funding agency that funds this particular project in that context.

PUBLIC SPEAKER: Project doesn't mean funded by an agency (inaudible.)

MS. WRIGHT: Okay. So what is our reach- through?

PUBLIC SPEAKER: They would notify NIH within (inaudible).

MS. WRIGHT: So the answer is that the ICDUR would notify NIH who would then triage the evaluation to the appropriate funding source. Okay.

MR. DIXON: Marci, Dennis Dixon from NIH, and so what I would say -- ad that's a good question. I mean that's why we're having this to come up with interpretations and questions that we hadn't thought through from the beginning. If there are federal funding entities, at the NIH, we don't duplicate funding of any other funding entity so I would think that the overlap question would have to be pursued and rarely would you expect the exact experiment to receive funding from any more than one place. It might require multiple notifications to arrive at that decision though.

MS. WRIGHT: Yeah, I agree. Thank you, Dennis. Any other comments or questions? Sherry?

PUBLIC SPEAKER: (Inaudible).

MS. WRIGHT: That is my understanding, Ryan, the --

PUBLIC SPEAKER: The non-federal (inaudible).

MS. WRIGHT: Yes, for the non-federally-funded research.

PUBLIC SPEAKER: Okay. And then follow-up on that, I understand that there is a back and forth time if it's been found to be DURC and you have to waive for a reply from the funding agency. If it is not DURC, it's been reviewed (inaudible) funding agency (inaudible) do we need to wait (inaudible) if they're like (inaudible) time (inaudible).

MS. WRIGHT: So do you need to -- does the research need to be put on hold until the funding agency affirms the decisional outcome of the IRE?

PUBLIC SPEAKER: (Inaudible.)

MS. WRIGHT: Okay. Absolutely. And so the funding -- so I'll go ahead and answer this question now. The funding agency has 30 days -- after the IRE provides its response, the funding agency has 30 days to respond to that IRE decision. And if the IRE is submitting a risk mitigation plan, the funding agency has 60 days to work with the IRE to finalize and approve that risk mitigation pln. But the question is if the

IRE says it's not DURC, then does the institution have to wait for the funding agency to affirm that? And I'll pitch that to our colleagues. What do we think? Dr. Burns?

PUBLIC SPEAKER: I had a different question.

MS. WRIGHT: So this is something clearly for us to discuss. Thank you, Sherry. That's water heaters we're here. Any comment on -- to follow-on to Sherry's point before I move on to Dr. Burns?

PUBLIC SPEAKER: (Inaudible.)

MS. WRIGHT: Where does the institution get funds to stand up the IRE, conduct the evaluation --

PUBLIC SPEAKER: -- you have a contract, you have a (inaudible) and you have this process that you're not sure is going to happen or now, how (inaudible) funds back --

MS. WRIGHT: Okay. So I want to make sure I understand your question. You're asking where does the institution get funding to support

the IRE processes and the development of a risk assessment mitigation plan; is that correct?

PUBLIC SPEAKER: Yes.

MS. WRIGHT: Any comments?

(No response.)

MS. WRIGHT: So this is an activity that the institution undertakes as part of its efforts to have a research enterprise with U.S. Government-funded work.

PUBLIC SPEAKER: (Inaudible) so your answer is yes for one of the 15 and yes for one of the 7 essentially (inaudible).

MS. WRIGHT: So are we -- is the U.S. Government requiring the institution to wait on a funding agency concurrence, non-concurrence or something before they can proceed with the research that they've determined not to be DURC? That's a good question. Any comments? I see Susan writing.

PUBLIC SPEAKER: (Inaudible). Is there a (inaudible) player (inaudible) financial updating for mitigation (inaudible) in order for

the ***1:33:27. It sounds like (inaudible) until we get a grant, the cycle is over, you run out of money, you can't run the (inaudible) or if you've already gotten far enough along (inaudible) acquire some money (inaudible) so either a subsidy of some federal -- if the federal government is proposing this (inaudible), would there be some obligation of (inaudible).

MS. WRIGHT: Okay. So just for the benefit of our web audience, the question is, is there a mandate that would provide funding support for risk mitigation and follow-on activities to support research that may no longer be funded or supported by the institution, so what happens then. And I think, Carrie, you had some comment.

MS. WOLINETZ: Well, on that, I mean I think there might be an opportunity depending on the funding agency's file (inaudible) extension (inaudible) but I was also going to say that for the earlier point of this timeframe, so the IRE says it's not DURC, okay, to inform the funding agency, what is the period of time that the

funding agency has to come back and say we agree or we disagree with that, you know, either move forward with the experiments or move forward with the risk mitigation plan process. I would be interested in hearing from our institutional colleagues what do you see as a reasonable timeframe for that? Is it 15 days; is it 30 days; is it 60 days? I mean how long is it reasonable to put an experiment on hold before you need to get the, you know, "red light/green light" to move forward?

PUBLIC SPEAKER: They've already been waiting (inaudible.)

MS. WRIGHT: So the one -- institutional representative have said, you know, my PIs are already waiting and if it's not -- if the IRE has determined that it doesn't rise to the standard of DURC, we don't want to wait. Jerry. And I'm sorry, I was looking for Dana and the -- thank you. Sorry, Ken.

MR. EPSTEIN: Hi. Jeffrey Epstein. I'm one of the federal partners here. I think this is

a very good question and I think you deserve an answer. I'm going to hazard this on my own but recognizing there are other people who can correct me, I believe that the policy is silent on that point. If there's nothing in the policy requiring the (inaudible) to wait, I don't believe the government can make you wait.

I think this is an issue that we're going to have play that through and see how it goes the first one or two times. I would hope there's a conversation with the funding agency anyway. So if the funding agency disagrees with the judgment, my interpretation is that the institution does not have to wait for an answer and can proceed.

If the funding agency says, wait a minute, there's a problem here, I would hope there's a dialogue and maybe in that exceptional case, we could talk to each other and maybe recognize a different outcome. But I don't believe -- if there's nothing specific requiring an institution to wait on a policy, I don't think

the federal government can impose that as an interpretation after the fact.

MS. WRIGHT: And we have -- Dennis, I think you have a comment. Please, Dennis. And sorry, Dr. Burns, I promise, we just want to maybe close this particular question out.

MR. DIXON: Thank you. You have to get here really early to get a seat at the back. I would agree with Jerry that you all deserve an answer to that question ad I would say heretofore, we have been approaching this form the government side first with the policy published March 29, 2012 where we were the first to look and define DURC. And we found out about it and notified the institutions. Now we have the situation where it's going to be more of a shared interaction, so it's the first time we've had that you are now expected September 24th tot making the assessment from the very beginning. And so if the project winds up getting funded, we will have been looking at it, too. So it's not like we're going to stop looking at things. We're going to continue to

look at things but want to do it together and want you to have the heads up as you're planning your research, as you're working with your institutions to do it on the front end rather than us, surprise, we've just looked at your grant and we think it might relate to the DURC policy. We're doing this together and I think we'll get -- we'll meet in the middle in a harmonious spot.

But I think you're right, Jerry, I don't think it's explicit at this point. It's something we can work through and make explicit if we think that's necessary.

MS. WRIGHT: Thank you, Sherry. Thank you for that. And Dr. Burns.

PUBLIC SPEAKER: So the question is if it is considered to be DURC, is it going to be able to be published?

MS. WRIGHT: So we can talk about that and we have an entire session this afternoon that's going to talk about --

PUBLIC SPEAKER: No. But I think the question -- this is -- a fundamental technical

question to me is since the NIH is the major funder and the NIH cannot support, by definition, classified research, how do you -- and I understand the journal issue is going to come up but I think that this is a basic question that needs to be thought about up front before it ever gets to the journal and that's what the journal editors will tell you anyhow when they get here.

MS. WRIGHT: Right.

PUBLIC SPEAKER: So the question is what are you going to do about a DURC positive?

MS. WRIGHT: Right. And so, you know, we talk about that. That's appropriate communication mechanisms, the responsible communication of the research. We talk about that at length in the risk mitigation piece and we'll be -- I think we have an entire session -- panel discussion dedicated to that later this afternoon. But yeah, so there are -- and as you know, Dr. Burns, there are multiple ways to communicate research findings, AIMs, long before we reach the manuscript and publication stage and certainly

those of us who have, you know, lived through the

understand the importance of working this out long before it hits the journal and becomes their property. Thank you for that. Any other comments?

All right. So it's 10:40. I think we close shop at 11 for this case study. So I want to go ahead and move on. So let's move on to risk mitigation. All right. So risk mitigation is the process of applying the institutional oversight life sciences policy to the research proposal to develop and implement a risk mitigation plan and manage both the research resources as well as the research information and yes, clearly, risk assessment is an integral part and a public health benefit risk analysis, which can be subjective, is a part of that process.

So moving on to page 12 of the case study, so having determined that Dr. Jameson's experiment does meet DURC, he and the IRE work together collaboratively to develop a risk

mitigation plan. The IRE takes into account considerations for appropriate biosafety and Biosecurity measures and Dr. Jameson approaches the IRE with recommendations of his own for the biosafety and Biosecurity measures that he would like to implement in order to conduct this research safely and responsibly. And so on page 12, if you can just take a moment to read those couple of paragraphs to look at the biosafety and Biosecurity measures that the IRE might consider and that Dr. Jameson proposes. So again, we're working with Francisella tularensis subspecies tularensis. Our OBA and BMBL guidance suggest that at a minimum, this is handled in biosafety level three conditions. So what are some of the considerations that the IRE might take into account to address laboratory biosafety and Biosecurity?

PUBLIC SPEAKER: Might consider some sort respiratory infections program --

MS. WRIGHT: Okay.

PUBLIC SPEAKER: -- PAPRs or N95s or

something along those lines as to (inaudible) --

MS. WRIGHT: Absolutely.

PUBLIC SPEAKER: -- inaudible) be infectious.

MS. WRIGHT: Absolutely. So the use of PPE including respiratory protection or PAPRs and -- which are PAPRS -- excuse me. Any other?

So that would be a control, a safety control. Any other measures?

PUBLIC SPEAKER: I think it's assumed here but the Biosecurity is not explicit. BL3 labs typically have a roster of people who can code in, badge in, or something --

MS. WRIGHT: Right. You have controlled access with --

PUBLIC SPEAKER: -- you have to deal with --

MS. WRIGHT: -- the biometric reader.

PUBLIC SPEAKER: -- (inaudible) aspects as well as the safety.

MS. WRIGHT: Absolutely, and this is still a select agent, you know, that we're working

with so we're -- excuse me, I'm sorry -- we are working in the context of what the select agent program would require for a tier one select agent. Any other considerations, biosafety and Biosecurity measures.

PUBLIC SPEAKER: Yeah. This would, I think, tie into a little of both. You could have enhanced monitoring of the laboratory either with, you know, security cams or you may want to implement a no loan rule for, you know, a high -- potential high impact --

MS. WRIGHT: Okay. So enhanced --

PUBLIC SPEAKER: -- (inaudible).

MS. WRIGHT: -- enhanced cybersecurity individual, monitoring measures above that that's required for tier one agents, okay. Any other?

PUBLIC SPEAKER: (Inaudible.)

MS. WRIGHT: Very tight inventory control with duplicate redundant systems or double-checking.

PUBLIC SPEAKER: My comment here is I don't know that IRE should necessarily be worried

about this because this is a select agent. You will not find tularemia SHU4 in a non-registered space. In order for us to registry the entity for this work, all those things that are mentioned will already be in place, restricted access, you know, all measures will already be in place because we will not have this organism elsewhere.

MS. WRIGHT: Right. So this is a tier one. I would say that there might be an argument depending on risk assessment and what Dr. Jameson -- the procedures that Dr. Jameson is doing and the personnel doing them that there might be an argument for increasing the containment level from BSL3 to BSL3 with specific enhancements. But yes, this is a tier one select agent so much of that is already going to be in place.

PUBLIC SPEAKER: So I have two comments. One would be -- I think another important element would be the occupational health program in the house.

MS. WRIGHT: I'm sorry.

PUBLIC SPEAKER: Occupational health,

occupational staff, OR staff monitored, etcetera, etcetera. And to the point just raised about these things are already in place, absolutely, it's a given, but I think that becomes important when we communicate the findings because the public doesn't understand necessarily what type of measures we are putting in place to protect the research if you will.

PUBLIC SPEAKER: (Inaudible.)

MS. WRIGHT: Absolutely, occupational health is a requirement for the tier one agents already, yes.

Okay. So Dr. Jameson just mentioned that he could put in place specific engineering and administrative enhancements. He talks about ensuring that the work is done in a BL3 lab that has dedicated air handling, HEPA filtration on the supply and the exhaust, pass-through autoclaves and dunk tanks, and then additional administrative requirements for shower in-shower out, for example. And again, I appreciate your comment because it is very important that we are dealing

with a tier one select agent that, you know, already has a baseline for expectations for biosafety and Biosecurity. Any other comments? Dr. Ellis.

DR. ELLIS: (Inaudible).

MS. WRIGHT: No shower in, okay. Shower out, okay.

PUBLIC SPEAKER: (Inaudible.)

MS. WRIGHT: So ensuring that the incident response plan that exists because it is a select agent also has a piece to it that says this particular strain might have an enhanced public health consequence. Would anyone not put their in their incident response plan, that it's particularly a DURC strain? Okay.

All right. So let's go ahead and move on. We've got about 10 minutes. Hopefully, we can get through this. So the IRE also considers medical countermeasures. Let's go ahead and look at page 13 of your case study. So there are multiple medical countermeasure considerations that the IRE might wish to consider or should

consider, first asking the question, do medical countermeasures exist for this bacterial pathogen? Is the new strain susceptible to these medical measures? And what is the degree of effectiveness of these medical countermeasures against the strain when compared to strains that have been more fully characterized?

So Dr. Jameson provides some information. So I'm at the top of page 13. He provides some information that -- he indicates ion his comments to the IRE that no new antibiotic-resistant traits are being introduced by modifying the surface protein. He anticipates, anticipates that the new strain will be susceptible to the standard antibiotics; however, he does acknowledge that it's not known of the antibiotics are as effective against the new strain.

So here's a question. Should the IRE conclude that existing medical countermeasures are sufficient based on the information that Dr. Jameson provided? If so, why? Are there other considerations or do they have enough information?

And I'll go to the back.

PUBLIC SPEAKER: So for tulli, you know, antibiotics aren't the only MCM available. There is an investigational vaccine. So the question is are the personnel vaccinated? If so, that's a potential mitigating factor.

MS. WRIGHT: Right. And so that goes to Joe Kanabrocki's point about having an updated occupational health plan and monitoring. Yeah.

PUBLIC SPEAKER: (Inaudible.)

MS. WRIGHT: Trust --

PUBLIC SPEAKER: -- (inaudible).

MS. WRIGHT: That's an outstanding comment. The comment was trust but verify, asking the investigator to show a minimal inhibitory concentration assay that verifies that the strain is susceptible or as susceptible as earlier strains to the frontline antibiotics. Thank you. Outstanding. Okay.

All right. So, being cognizant of the time, I want to go ahead and move on to risk communication, Dr. Burns.

(Laughter.)

MS. WRIGHT: Okay. So, and this is going to get interesting. All right. So on page 15, we learn that the IRE and that Dr. Jameson are describing well, how can we develop a communication strategy that consistently upholds in the responsible communication of DURC research. The IRE should consider communications that may occur before publication. At what stages, Dr. Burns, in the research continuum might communication about research occur?

PUBLIC SPEAKER: I'm worried about this whole setup because if it's really DURC and the implications that are in DURC, then the question comes of where you want that information to go and that's a touchy subject. I mean we fought through this for quite a long time and we didn't come up with a useful answer at that point. And, you know, in a sense, and it may not be classified at the highest level, it may be just for so and so individuals, but it's unclear to me how some funding agencies, at least one that we know about,

are really going to be able to fund research according to its current mandates under those conditions.

So the real question I have is if it's really DURC, does it have to go to a different agency which is well-able to handle restriction of publication? That's the way I think about it and, you know, who you decide to tell before you do formal publication, I think that gets kind of iffy, especially if it's, you know, dealing with select agents and you've got the people who are administering that program to contend with. So all I'm saying is I think there needs to be a very clear policy about exactly this issue. I haven't seen that yet. Maybe you're going to tell us but I think it's a difficult question.

MS. WRIGHT: No, I'm not because we are still having these discussions internally.

PUBLIC SPEAKER: That's what I'm worried about.

MS. WRIGHT: No. Right, but I understand. I understand but the basic non-

initiated answer is that communication can occur in several fora before we actually reach a paper so lab meetings, you know, calls with collaborators, posters and presentation sessions at societies or symposia, so that's the uninitiated answer to that question. But yes, we have to think where do we go with this at the very beginning and at the funding level, absolutely.

PUBLIC SPEAKER: Have you considered a new journal called the "Journal of Dual Use Research" which is limited distribution and only among people who do this type of research so that we can communicate with each other and then determine if this really, really should be published, you know, in regular circles.

MS. WRIGHT: Any comments?

PUBLIC SPEAKER: In these days of internet communication, what is to stop the key elements from circulating? In these days of internet communication, what is to stop people from communicating the key elements on the internet, not as a publication or others in --

MS. WRIGHT: Right. So just internet media, yeah. So here's what Dr. Jameson proposes. Ask the funding agency to review his manuscript to provide guidance on responsible communication. Any thoughts on that? That's number of two of my murder board question. Okay.

Describe -- so when they -- when he does communicate the research in whatever fora and in every fora that he might communicate this research, describe the biosafety and Biosecurity measures that were used to conduct the research, so say this is what's occurred din biosafety level 3, BSL3 enhanced settings with these particular hierarchy of controls, communicate that. And I know investigators are already doing that happily.

Emphasize the public health benefits of the research including how medical countermeasure development might be improved. And this, I would say, would include a discussion on the risk assessment process, the criteria for the risk assessment and how the institution in collaboration, as Dennis said, with the funding

agency and the PI came to finalize their risk analysis and move forward with the research model or modified research.

Communicate research results consistent with best practices in the responsible conduct of research so having an objective approach and truthful approach to communicating the findings and the significance of the findings to the public health world. Any other comments? In the back, got four minutes.

PUBLIC SPEAKER: (Inaudible.)

MS. WRIGHT: So the question is for some agencies, are some agencies leaning toward a policy that if the research is identified as DURC that they will move to classify the research; is that correct?

PUBLIC SPEAKER: So this is Chris Viggianni from NIH. I help to manage the NSABB. I can't speak for all of the agencies but I would just channel the NSABB over the years. What they've pretty consistently said is that just because something meets the definition of DURC

doesn't mean it shouldn't be conducted and does not mean it shouldn't be communicated. In fact, they've said the vast majority of DURC should openly conducted, openly communicated, and that it can be managed with some of the risk mitigation measures we're talking about today. It's only in the really rare circumstances where redaction has even come up in the discussion. And I think moving forward, that's still the anticipation. As far as classification goes, the challenge is retroactively classifying and that's why it's really important to have these discussions up front at the time that research is being funded and throughout the course of the research. So if there is an unexpected finding, you're in dialogue with your funding agency and you can make wise decisions about which way to go to with the communication.

MS. WRIGHT: That is the answer Dr. Burns was looking for. Thank you, Chris.

DR. EPSTEIN: This is Jerry Epstein again. I just want to remind people what Dennis

Dixon already said earlier. This is in the context of another policy which is incumbent on the funding agencies to think about this sort of thing before things are funded. So if there are projects that are going to -- likely to raise these sorts of questions, the funding agency should have those conversations before the money ever goes out the door.

MS. WRIGHT: And thank you for that segue. HHS actually does have a gain of function funding framework for specifics sets of gain of function experiments related to pandemic potential influence -- subset of influenza viruses so that framework is on a phe.gov.s3/dualuse. Go ahead, got couple of minutes.

PUBLIC SPEAKER: I'm curious in talking about implementing these policies. Are they considering -- so when you apply for funding and you're going to be doing animal research, you have to have your protocol proof first; or if you're going to do human research, you have to have your IRB approved first. We're talking about having

this sort of DURC assessment and risk mitigation already in place when it's submitted to the funding agency?

MS. WRIGHT: Right. So another way I might ask that is how do we ensure that all of our compliance review committees and processes are integrated to ensure that once a decision is made, yea, move forward with the research, that everyone who is a stakeholder is apprised and has similarly approved. So we would want our IACUC, our IRB relevant, our IBC, and the IRE to ensure that they are tracking together and would recommend -- and we've actually, in other policy recommendations, development of set, we really want to see these committees and processes cross-fertilized with the appropriate subject matter experts and governance-responsible authorities.

PUBLIC SPEAKER: Just a concern to raise about the communication of these results, especially the biosafety-biosecurity and public health benefits. So as you noted, a lot of this is going to be done in the context of the risk and

benefit assessments conducted by the IRE both to establish whether this is DURC and then to establish the risk mitigation plan. However, historically, IRBs and IBCs have not been transparent in the ways that they conduct their behaviors and the decisions that they make. Is this setting up a precedent to actually communicate with findings what the types of decisions are being made in order to get this from -- input from kind of conception to publication, or is the IRE going to remain similarly opaque as its cousins, the IRB and the IBC?

MS. WRIGHT: So I'm going to refer to OBA on that for sure. My understanding is that -- at least I'm a biosafety background -- IBC minutes are readily available but I'll defer to OBA.

PUBLIC SPEAKER: Yeah. So in terms of -- I can't really speak on behalf of IRBs because our office oversees institutional biosafety committees, but institutional biosafety committees are predicated actually on the principle of transparency and openness. I'm sure many people

here are familiar that IBC meeting minutes are available upon request. The majority of IBC meetings are open to the public. We encourage IBC meetings to be open to the public when there's not a private or proprietary interest being represented and actually, members of the community are actually members of the IBCs so it is a requirement that two unaffiliated members of the -- - unaffiliated from the institution be members of the IBC. So I'm not sure I would characterize IBCs as not being transparent.

MS. WRIGHT: So I think a question might be what IRE proceedings have minutes that would be publicly available. I think that's a good point to put in.

PUBLIC SPEAKER: There is a --

MS. WRIGHT: We support -- I should say that we support transparency.

PUBLIC SPEAKER: And the processes that an IRE follows are required to be made public. That's part of the policy, that the actual policies and procedures that an IRE follows are

publicly available upon request.

MS. WRIGHT: Thank you, Ryan. All right. I just want to wrap up. We're a couple of minutes overdue. If you'll please forgive me for going over. So I just really want to quickly say this because there are a couple of prescriptive remarks in here. So in developing the risk mitigation plan, as we know, training is an integral part of that and refresher training is an integral part of that. This afternoon, we're going to talk about education and training at length during the panel discussions so the panelists can circle back on this.

But I just want to say that the institution and the PI are required to provide education and training on the institutional DURC oversight policy for any individual conducting research with one or more of the 15 listed agents. This is irrespective of the type of research that's being done. So if they're working with one of those 15 agents or more, they need to have DURC training and they need to have it annually.

Okay. All right. And so I did mention this earlier that we do have a responsibility as the federal government, as funding agencies to engage positively in the dialogue and close communication circles. So we must provide responses to the IRE, risk mitigation plan within 30 calendar days and finalize that plan within 60 calendar days. And I know that we have a question and further exploration on the question of what happens if the IRE says this is not DURC.

Great. Any other comments before we sign off for the case study? Thank you so much. It's much appreciated. Thank you.

(Applause.)

MS. WOLINETZ: For those watching on the webcast, we will be back at 11:15 to continue the meeting.

(Whereupon, off the record at 10:32 a.m., and back on the record at 10:57 a.m.)

DR. EDWIN: We'll start the next session in about a minute and it's time to return to the

seats, please. Okay. Welcome, all. This session is going to focus on reviewing and identifying DURC, you know, the processes that are in place. We have three fine panelists. My name is Sam Edwin. I am from USAMRIID and I am also the responsible official for the select agent program there. I have been involved playing a role in DURC processes at our place since 2011 when the first policy came about.

Without further ado, let me introduce our first speaker. It's Dr. Trevor Ames and he's the Dean of the College of Veterinary Medicine, university of Minnesota.

DR. AMES: Thank you, Dr. Edwin and good morning everyone and thank you to the meeting organizers for inviting me to be part of this discussion. I look forward to learning from my fellow panelists as well as the members of the audience during the discussion.

So I will try to address both what is happening at an institutional level at the University of Minnesota as well as at a collegiate

level and I think, certainly for DURC policies and procedures, there is a need for obvious U.S. Government oversight. There is need for institutional oversight, and the collegiate units also need to be actively involved to aid and identification and compliance.

The potential threats from research that falls under the purview of DURC cannot be overstated. Certainly, human illness and deaths are front and center in everyone's thinking but catastrophic animal and plant disease and the effects that that have on our food supplies must also be considered.

Coming from Minnesota, it's easy to look at the recent high path avian influenza outbreak that devastated our poultry industry this spring. This disease was caused by H5N2 and it affected birds in the Midwest as well as the West Coast, and it was the most severe foreign animal disease incursion in the history of the United States. In Minnesota alone, there were 108 farms that were affected, lost over 9 million birds and cost to

date $650 million dollars. The disease produced a 95 percent mortality with death loss occurring in 5 to 7 dates, created just extensive regulatory issues. We had 108 control zones in the state around the quarantined farms and as you can see from this map, the control zones took up a large part of the state that coincided with our poultry producing areas. So this created just lots of regulatory issues.

And from early research, it appears that this disease was spread by aerosol following wind events and this represents a new biosecurity threat in our control programs.

So as this outbreak was progressing and I was spending time at the State Capitol talking to legislators and thinking about the request to come to this meeting and talk about DURC, I was also thinking what if this were the headline in the news. And so in addition to other concerns and outcomes that have already been mentioned, if research surrounding DURC was not properly managed, there wasn't sufficient oversight, I

think this would just have devastating affects at land grant universities and possibly even on federal funding. But just to be really, really, really clear, this is a hypothetical headline.

(Laughter.)

So I just also want to highlight how important the food system is and emphasize the need for DURC policies and procedures to be aware of and able to detect and manage potential research threats in this area. It is one of 14 critical infrastructure sectors identified by Department of Homeland Security. So I understand the need -- that the initial list of agents, toxins, and types of research that are being considered are certainly most important for initial policy and procedure development, but as we develop our oversight policies, I think there must be the ability to detect broader risks as they arise.

It's important for our institutional oversight to identify and discuss the benefits and risks of the research before it's conducted and published. Institutional oversight must be able

to identify the DURC agents involving the 15 agents and toxins and the type of research that presents a risk with these agents.

But I would point out that oversight policies and procedures relying solely on the proposal routing forms might miss research that's funded through research faculty startup packages. Oversight policies and procedures that are triggered by the 15 agents and toxins might miss other research studies like something -- a study that dramatically increases the dissemination of UG99 in wheat crops. And oversight based on research safety officers that are tined only for a particular college might miss atypical research for that college like a college of engineering faculty member that is working on engineered organisms.

Numerous units at Central University of Minnesota have a role to play in this including, obviously as has been mentioned, the institutional biosafety committee that reviews research with animal and plant pathogens and toxins of the risk

two group and above, the Department of Environment Health and Safety that conducts our annual laboratory inspections, the BSL3 director and staff, and obviously the Office of Sponsored Projects Administration that has pre-award oversight and ensures that proper compliance on those submissions.

Also, I think oversight at the collegiate level is equally important with knowledgeable PIs and lab self-identifying projects, well-informed department research officers who conduct regular lab inspections and would recognize research of concern, and the department chairs and associate deans of research also using their oversight role when they're approving and forwarding projects.

And I think there are educational opportunities that could be really important at the institution and collegiate level. Certainly, the University of Minnesota's "Responsible Conduct for Research" program provides a great venue for delivering educational materials for all parties

and as has been mentioned earlier, to be eligible to be a principle investigator, there is a core curriculum plus targeted curriculum so integrating a DURC educational program would be essential.

So I think universities also have a tremendous wealth of human resource available that they can be tapped into when they're putting these committees together or consulting on issues presented to these committees with lots of universities having past members of the National Science Advisory Board for Biosecurity, the NIH Recombinant DNA Advisory Committee and just faculty members that are known to have expertise in toxins, plant and animal pathogens that can all provide useful guidance.

So thank you for this opportunity.

DR. EDWIN: So after (inaudible) we'll take questions. So the next panelist that's going to be doing a presentation is Dr. Robert Ellis, and he's the Director of Biosafety, Colorado State University.

DR. ELLIS: Thank you very much, Dr.

Edwin and Dr. Monarez, thank you for the invitation. I really appreciate that and thanks for the opportunity here today. We've already learned a lot so I think it's going to be a very good day here.

This is the list that you've already seen. This is a list of the 15 agents that we must consider. If we are working with one of those 15 agents, then it must be considered, as far as the potential dual use research of concern. And at Colorado State University, we're working with 8 of those 15 agents, so we definitely have some concerns. Whether they're dual use research of concern or not, then that's what we need to determine after that.

In 2009, we put a question on our biosafety protocols that the principle investigators submit to the IBC that asked if any of the research that they were doing was dual use research of concern. It was just a "yes" or "no" question. So, in 2012, there were those two papers on gain of function of high path avian

influenza. Again, 2012 -- or another thing in 2012 was when the U.S. Government oversight policy was put forward and then in '14, the institutional policy for dual use research of concern was published, and that goes into effect in September of this year.

So, we have added a lot more detail to our project approval forms and the project approval forms are what must be submitted and must be approved before any of the research can commence. We have close to 500 project approval forms. We've got over 1,200 total project approvals active at this current time, but the projects themselves, the active part, there are about 500 of those and about 127 principle investigators of those agents that people work with, about 150 different agent approvals are in existence for those 127 principle investigators at the either level of Biosafety Level 3 or with select agents.

So in the current project approval request form, we have put in all seven of those

criteria that are listed that must, one of those at least, must be fulfilled if there is going to be dual use research of concern in a particular project and those are not just are you working with one of these. Each one of those has a yes or no answer and currently, they're either defaulting to yes so somebody must consciously change those to no or we're going to leave them open so that they can make a yes or no choice. I favor having a yes on there that people have to change consciously to no.

Then also, right at the top of that approval request form, very, very top in a yellow highlighted box in big bold letters, "if you're research involves use of recombinant and/or synthetic nucleic acid molecules, please read the following before you submit this form." And in this form, it said, "And should the assembly of novel molecules produce an unanticipated product that increases virulence or toxicity or otherwise confers a phenotypic change that would be biologically hazardous, I will notify the

biosafety officer and IBC immediately." So we have that statement right in there, right at the top for people to look at, and it doesn't say is it one of these agents that lists the 15 agents, and it doesn't say does it fulfill all these criteria. This is before you even get to any of that. It says would this confer more hazards to this particular research.

So at Colorado State University, our institutional review entity is the current existing standing IBC. We've got about 15 members on that covering a whole spectrum of research expertise. Then our vice president for research is the institutional contact. And as I told you, the investigators are notified thro ugh that system.

But also, further to that, in my opinion, we do have some potential dual use research of concern not on this list outside of those 15 agents and outside of those 7 criteria. They may fulfill some of those 7 criteria but definitely outside of those 15 agents. The mouse

pox research that was mentioned earlier was not one of the agents that are on our list so what if somebody did some research similar to that with an agent that's not on the list? What about publications such as the botulinum toxin in the milk supply, some other toxin that's not on the select agent list or in -- well, it could be on the select agent list but the only toxin on the 15 list is Botox or botulinum neurotoxin. What about other gain of function, expanding a host species for something that would be of high agricultural incident or importance that is not that list. And I think from a principled standpoint and an ethical standpoint, we need to also look at some of those as they come up and not just be focused entirely on the ones that we have.

Another concern of mine that came up this morning is also the timeline here, and we've already seen from a research standpoint that if there is dual use research of concern even at the local level, if the review entity says "no, it's not," we still have to make that notification to

the funding agencies. But if it is a "yes," then we've got 30 days or 60 days or 90 days or, you know, you keep adding those up month by month by month and that's a real impediment to research that's already struggling to a certain extent to get the work done that's really important.

So I'll leave it with that and turn it over to the next speaker.

DR. EDWIN: Our last panelist for this session is Dr. Philip Potter and he's from St. Jude's Research Hospital.

DR. POTTER: So I guess I'm the fly in the ointment here. I come from a children's cancer hospital and you're probably thinking why am I here. Well -- so the reason we do that is we have a very large flu program at St. Jude, so we have two large grants that provide funding to two investigators who essentially run two independent groups. One is NIAD- funded and the other is WHO and essentially, what we do is we take flu samples from around the world. We categorize them based on their genotype. We figure out if they're high

or low pathogenecity based on the influenza type and then we do biology on them, okay, and because highly pathogenic influenza virus is one of those regulated by DURC. It was obvious that we had to set up a program to do that.

Now we do very little DURC research in the sense that we're not -- I'm trying to understand a lot about the biology of these viruses. A lot of it is just categorization for finding out what the sequences are, what might be the key residues that are involved in pathogenecity, but we do swap viral segments into low path virus to understand some of the biology, so that obviously falls under the category of DURC.

So how do we identify that at St. Jude? So we have a very similar system, it sounds like, to those at Colorado State. We have an online submission form and I don't intend you to read this but this is the section that comes from the NSABB that raises all the issues that come up. And again, we have the seven questions that relate

to the seven characteristics that have been discussed previously today. So answering "yes" to any of those questions regardless of pathogen triggers review by the biological safety officer and myself. If they're working with a non- DURC agent, you know, we go back to the investigatory, figure out what they're going to do, figure out if there really is any DURC component to it. If it does, then it goes on to the full DURC committee review but in general, that doesn't happen.

All of the stuff that we have review ed so far has been through high path flue that have come in. At the same time, all of the protocols distributed to everybody on the IBC, anybody can suggest I think this might be DURC. If that's the case, it automatically goes to DURC review regardless of what the question was. And we've always reviewed all of the high path research at St. Jude, even if these questions are answered "no." It's always overseen by us because scientists get so engrained in what they do, they might not see something very obvious to somebody

else. So we always look at the possibility of DURC.

So our subcommittee is, I think, somewhat unusual but I think it's good because it brings different expertise to the table that has helped us quite significantly. There's myself, a vague expert in this field. Then we have faculty who are obviously experts in the science that is going to be conducted. Because that's only flu at St. Jude, that's quite easy for us to choose from. We have probably 10 or so flu researchers who know enough about the experiments that are being done that can provide a valid opinion.

We have a biological safety officer, director of EH NES (ph) who is also our select agent program manager. We have somebody from IRB. You may think that's odd but we are a children's cancer hospital. Everything that we do has some impact on children's health somewhere. We always have patient concerns as one of our outcomes.

We have people scientific editing and as I mentioned earlier, we do that because at some

point, this information is likely going to be published. We want them in at the front end so that they can understand what the science is, how it needs to be communicated and the best way to do that. If we get to a risk management procedure, then we bring in communications and PR people to manage that.

And we also have legal counsel. We have that because there are indications where when you collaborate with other institutions, you want to make sure that those other institutions also follow the DURC review that has been undergone at our institution. So it's a legally binding situation. It is negotiated between our legal counsel and legal counsel of the collaborators.

The PI submits the protocol. We review it in advance. it's usually a pretty lengthy meeting, lots of science questions, quite a few non-science questions about how this would benefit -- what the risks and the benefits would be. So I think we go through this in quite detail. Most of what we ask, of course, is based upon the

algorithm, you know, the 15 and the 7. We then vote and then based on that, we get minutes that are submitted to IBC and then the IBC look at those and based on that, we made a decision.

So there are problems. You know, we've run into two big problems that I think need to be borne out. The first is that one of the criteria in that seven says "alters the host range or tropism of the agent." So if you have a flu virus and now it no longer infects a chicken or a mouse, that automatically becomes under DURC purview because you've reduced its tropism, you've altered its tropism, so we are reviewing a lot of protocols where people are making virus that are less pathogenic, have different tropisms than the parent virus. That's become a pain for us because we know in advance that that's what we're going to have to review and we have to explain to the investigator that this would be categorized as dual research, not of concern but it would be dual research because we've altered the host range. If that said increased, we would be fine but alters

changes the ballgame for us.

And then the second thing that's come up is that H7N9, this is the nasty flu virus that's circulating in China and it's killed about 50 percent of the people it's infected. It's not categorized by DURC because it's not highly pathogenic. It doesn't kill chickens so it's not considered a DURC agent. We had an example where somebody wanted to modify some H7N9 virus at St. Jude based on some computational studies. They assumed that because it was not one of the 15 agents, it wouldn't be DURC. We flagged it for DURC and we reviewed and we said that it was DURC in lower capital -- in lower case. And the reason was because it didn't meet the criteria but we were just as worried about making that virus than anything else that anybody would make.

This was not a concern with the individual doing the science. The biggest concern was with our institution because now we'd created this new category, lower case durc, and people didn't know how to respond to that and we didn't

know either. We just knew that we didn't want that information publicly disseminated because it wouldn't take much to put two and two together to do the same studies on a highly pathogenic virus. So I think that's where I am, so thank you.

DR. EDWIN: All right. It's time to open up for the questions. The questions can be for any one of us or comments hat you may have. For our viewers on the web, there is always the durc@ostp.gov to send in their questions. With that, I will just open it up for questions.

PUBLIC SPEAKER: (Inaudible.)

DR. POTTER: Fortunately, I think -- we started our DURC committee in 2012 -- I think we've only reviewed maybe six protocols in that time. People in the flu field know what's going to happen. The vast majority of their science is being directed away from that, good or bad. The other thing is that we don't do that much science that specifically looks at those properties. The vast majority of our science is surveillance and so, really, we don't do that much DURC science.

But I could imagine in a big institution, if you've got a lot of protocols to review, it could be a very time-consuming process.

PUBLIC SPEAKER: (Inaudible).

DR. ELLIS: Since 2009, when we've had that question on the protocol, and remember only about 500 of that 1,200 would be open for dual use research questions, we've had three people check yes, possibly it could be dual use research. And as we used our own criteria -- that was before the criteria were available that we have now -- when we used our own criteria, it would be a real, real, real stretch to have made it that because it wasn't enhancing, it was we were dealing more with pathogenecity and someone would have to take that and really twist it to turn it into dual use research.

But now with this, I can see it getting more complicated. I still think that most of the time, it's going to be probably not dual use research once we look at it, but like I said, with eight of those agents in active research

protocols, then I'm sure we're going to have a lot more of them to look at. And as far as bottlenecks are concerned, we'll do our best to not have bottlenecks. I'm not so concerned with the bottleneck at our end as I am if we go to a federal agency and say "here's what we have, we may have some concern" and getting a response from the federal agency back in a timely manner, to me, is a bigger concern than at the local area or local level.

PUBLIC SPEAKER: (Inaudible). Oh, I have a question regarding clinical research (inaudible) medical institutions where people are using Botox but it's off-label; are you going to be looking at that because it's FDA-approved so under the select agent standard, it would theoretically be exempt, however, by using it off-label, so it's not approved for that particular use, how are people handling that?

DR. EDWIN: I think the policy says that if it is used for clinical purposes and if it is exempt quantities, that it doesn't come under the

DURC. Am I --

PUBLIC SPEAKER: It's select the --

PUBLIC SPEAKER: -- (inaudible) any quantity.

DR. EDWIN: Any quantity in research setting but I thought there was an exemption.

PUBLIC SPEAKER: In a research setting?

DR. EDWIN: Yeah, in a research setting --

PUBLIC SPEAKER: ***2:32:03(Inaudible) in a research project (inaudible) --

DR. EDWIN: Right.

PUBLIC SPEAKER: Well, if it's an IRB, it's de facto research.

DR. EDWIN: So if it is classified as research, yes, it will be -- it has to come under DURC.

PUBLIC SPEAKER: (Inaudible.)

DR. ELLIS: At our veterinary college, we do have some clinical research using botulinum toxin and some of the innovative research there wants to use that with a targeted mechanism of

tumor control or tumor destruction. And even though it's well under the toxin limits as far as the select agent program is concerned, there still is a stewardship SA gram (ph) it is called or a policy from the select agent program that even if you have it under that, you must somehow make sure that people aren't ordering limits below the threshold from different sources and then building it up to over the threshold.

DR. EDWIN: It's the due diligence policy.

DR. ELLIS: Right, definitely the due diligence fits in. Now, from another standpoint, and this is evident for us also, we are approved for producing botulinum toxin, storing botulinum neurotoxin, and it's well above the levels that are considered select agent so we've gotten select agent approval for that but we also have to show that other researchers are not getting transfers of those select agents, intra-entity transfers, not inter but intra, within from one of our PIs to another PI at Colorado State, that they're not

getting enough to go above that threshold and that we know where every microgram of that is at all times.

Also, just as an exercise, a few years ago, we had a canine clinician that wanted to use Botox, like I said, for anti-tumor therapy and I worked with a pharmacist to figure out units and converted to micrograms or nanograms, and it would take a truckload of Botox to get to the threshold level. I can't tell you how big a truck but a lot. And it really surprised me when we made that conversion and we worked back and forth several times to make sure we were accurate because the amount in a Botox vial, it's just so little that you just can't hardly have enough on stock to go above that threshold.

DR. EDWIN: So one request we have because it's a webcast, if you have a question or a comment, if you can wait for the microphone or go to the microphones, it would be appreciated.

Going back to these exempt quantities, you know, of entities that have a select agent

program, we have really good visibility on the select agent levels. So applying any quantity of Botox to be vigilant for DURC, it really calls for, you know, a reassessing and making sure that that due diligence for every exempt quantity is assured and to monitor those studies becomes really important. Because we have such registration and also people working with exempt quantities, we look at every research protocol for that reason.

DR. POTTER: I have a question for the agencies. So how would a new DURC agent be identified; who would make that decision; what would the criteria be; and how long would it take to implement?

DR. EDWIN: I think that's a good question. As the policy develops, you know, we fully expect -- I can give an example. Some of the things that were talked about by Dr. Potter, while we look at these 15 agents, we also actually look at MERS and H7N9, and I know there are others on the horizon. And the question is what about

another DURC agent. We fear that and that is one of the reasons that the Department of Defense at USAM -- I speak for USAMRIID and, you know, I'm not endorsed by the Department of the Army or the big DoD -- but we think it's prudent to look at every protocol because a lot of times, like it was mentioned, the PI is really focused on the very specific question that they're trying to answer, and it's better to have in addition to the investigator, another scientific team that can really look at all aspects. We have two independent reviews. We -- because of the large select agent program that we've had and the team that we have, me, as a responsible official and the team that I have, we've taken charge of actually looking at all the -- reviewing every research protocol right at the inception and also for operational security at the end of that to close that loop but it may not be a solution for everybody but, you know, we fully anticipate some of these agents may get added to that policy.

PUBLIC SPEAKER: Susan Coller-Monarez,

this morning, said that we don't want PIs to be censoring themselves. As I listen to your vast review process and with the policy to go into effect in September, do you have any sense that this is happening or fear that it will happen once the policy is instituted?

DR. EDWIN: I can speak for myself. I mean -- and because all of these agents are select agents, I have a very good relationship with all individual investigators. And, you know, one of the things that also helps is when we're reviewing for DURC, if we really don't have that communication with the IBC, IACUC, and the committee that is reviewing and the responsible official, the time gap to be able to assist the investigator is going to prolong. So many a time, we have -- when we're evaluating a protocol, we're able to call in not just one or two but three or four SMEs for that particular agent and to get the PI involved, and it's actually the things that we have done thus far actually have benefitted the investigator and cut the time really short, and

everybody participates in, you know, trying to come up with -- do the risk mitigation as far as coming up with the plan.

So I think that the primary goal should be not to make this policy restrictive but at the same time, we must follow the regulation and to be able to assist as a group and reach out wherever we need to reach out so that the PI feels included and no negativity attached to -- you know, so, oops, I've got a DURC protocol. And that's the approach we've been trying to take.

DR. POTTER: I think that at St. Jude, we do struggle with that problem because there is a lot of press at the moment about flu being bad; gain of function is coming down the pipeline. There are viruses probably circulating in the environment that are worse than what we work with in the lab. And so the perception from the public's point of view is that what we do must be bad. That makes it difficult sometimes for scientists to want to do the key experiments, I think, because they're put under pressure from a

lot of people about whether they do -- whether they really want to do that experiment.

So I think the PIs try not to do the DURC experiment in the flu field because at the moment, you know, this is -- this could be the next pandemic. So everybody is concerned about that, but when you balance the risk of the information that we would get from that, it would have to be beneficial. It's just at the moment, I don't think the public perceives it in that fashion.

MR. KOZLOVAC: Hi. Joe Kozlovac, USDAARS. I'd be interested in hearing from the universities, no necessarily so much from USAMRIID, but from the universities related to have you received more funding or resources, because it seems like your institutional biosafety committees have been taking on a lot of this kind of role or a subcommittee; so what sort of resources, training has your leadership provided to you for this type of activity?

DR. AMES: This has all been handled

under the existing support for the IBC to date.

DR. ELLIS: We have very good support from our Vice President for Research but I haven't seen more dollars and I don't think we will. I think it's more of a, you know, definite support and that's very important to have that. But also, the IBC is going to have more responsibilities, meetings are going to be longer, may have to have more interim meetings, not just a monthly meeting. I think there's going to be a little bit more, maybe quite a bit more -- I haven't seen yet -- I'm the RO and also biosafety director so there may be more there may be more load there, and I don't know where we're going to handle that or how we're going to handle that, but I know we'll handle it and we'll do what we can to not impede the research.

DR. POTTER: While we're technically not a university, we have employed two new folks in the last four years, one who is now the BL3 manager since he manages all the protocols, the activities that occur in the BL3, principally

through the IACUC. And we've also just employed a new person on the IBC who essentially shuffles all the paperwork for us because even though it's all done electronically, we have to maintain records of all this information and get it circulated to everybody so we have employed two new people for that.

DR. EDWIN: Comments from the audience on the university question?

PUBLIC SPEAKER: Tricia Delarosa (ph), NIH, and I'm was wondering from the university, first of all, it seems like your IBC is performing the function of the IRE, and so then I'm wondering about the information that comes out of this, is that freely available, freely disbursed on these projects that might be considered DURC?

And also, as a second question, I'm wondering about your threat assessment boards and if the threat assessment boards are being also trained on DURC in your universities.

DR. ELLIS: I'll start with the threat assessment and, no, right now I don't think ours

are trained on that outside of the IBC and outside of select agent program, but I think we can meld that into some very good sessions with risk assessment, with risk management at our university right across the hall from me and get that all implemented. I think it'll be a fairly smooth process. It's communication more than anything and get that done.

What was the first part of the question? Just shout it out.

PUBLIC SPEAKER: (Inaudible.)

PUBLIC SPEAKER: Oh, yeah, right. I was looking right at you when she was saying that thinking kind of already answered that. Yeah, I think there can be quite a bit of transparency on that as we go forward but also, I don't think that every little thing to mitigate and to withhold -- I don't know if withhold is the right -- you know, it comes back to some of the questions over here earlier on publications, how do we publish scientific research to the extent that it's useful and then yet still not publish it as a pattern on

how to do bad things with good research. So it is going to definitely be a balancing effect. As far as the minutes, we can -- I think we'll deal with that as we go through them and I'm more in favor of transparency than opacity but there has to be a balance there, too.

DR. POTTER: That's one of the reasons we made a DURC subcommittee, a subcommittee of the IBC because in those minutes, we have the presentation by the PI, we have all the nitty-gritty science. We don't really want the public and others who might be interested in it to know exactly the science that's going on. They can have the general overview of what's going on but we don't want to know exactly what mutations are being made, blah-blah-blah, because that might be, you know, information that could be very useful. So the minutes that are provided by our subcommittee contain the important information but they don't contain all of the details that are required to do the experiments.

PUBLIC SPEAKER: (Inaudible) so

you're not really going to want to have (inaudible) fully 100 percent as your IBC would because (inaudible) said, there might be things in there that might be (inaudible) might not want to leave in, so I think something to consider is (inaudible) that your IBC consider the processes that are unique to the IRB. Of course, I'm doing some overlap of the processes but really, you could think of the processes that are going to be unique to the IRE

PUBLIC SPEAKER: Hi. Patty Olinger from Emory University. To answer your question on that, what we have done is actually we have our IBC, which is also our research health and safety committee, where if you think about it, you know, there are a lot of things in IBC or biosafety that you don't have to necessarily review or you're not required to review in your IBC. And we require all of our research to actually be registered with the HS office. So our dual use research would be actually reviewed by a subcommittee of that, and we ran into this, you know, several years ago when

we all had to start submitting, you know, our -- when USA Today was, you know, asking for different things and everything, and our legal group actually came back and said, How are you -- you know, it gets to be very, very complicated in submitting all that paperwork and do we need to submit this or not.

So we ended up -- actually, we had the same group of individuals, to answer your question, and they review all IBC issues and then they close the meeting and then they reopen it as a biosafety committee or research safety because we also look at chemicals of interest as well or anything that has to do with research safety. And, you know, we're going to have another subcommittee underneath that to review any of those issues.

DR. HAUK: Phil Hauk, Icahn School of Medicine at Mount Sinai. We started in the business of DURC review when we got a little notification from the NIH saying, "Did you take a look at this H5N1 research and by the way, it is

one of these 15. Did you look at these seven outcomes?" So it would up being just a department -- sorry, the chair of the biosafety committee and myself looking at it, going through it, going back to the researcher and then writing a letter back to the NIH saying, "Yes, we looked at it. No, it's not DURC in this particular instance."

And then it became a subcommittee of the actual institutional biosafety committee with a few more people, four folks, and how it has evolved into a full separate we call it IDUCC, kind of like you duck when it comes at you. No, but it's Institutional Dual Use Concern Committee. We are separate. It's five people from the IBC doing another job. No, we're not getting any additional pay for that but a lot of patting on the head by the Dean of Research, go ahead and go forward and do thus.

And what we do is we advise the institutional biosafety committee. Our deliberations are kept separate so, of course, there's nothing to be publicly visible like

everything we post on our website for the IBC proceedings. However, some of that is still going to be there because we have to address each of the particular research protocols. They're identifiable by the GCO Number/NIH Number and also by the researcher. And it's going to say, "Is it DURC?" "Yes." "Has it been reviewed?" "Yes." So it's going to be out there.

And just one side issue to go back to something earlier, as far as looking at other agents that are not on that list of 15, we had this 10 years ago. One of our researchers was working with vesicular stomatitis virus and what they were doing was putting magic bullets in it to go kill human cancer cells and you're going to go stick this in human beings. So, like, uh-huh, this is change of tropism for VSV and we sent back and asked them, "You looked at the model, which efficacy?" And we had to take a look at all their phase one and phase two data in that before we said go forth and use your agent.

So you did have that rubric originally

in the section three. If you went through the NIH guidelines, what was on the section three, you have some indication there. But I'm glad to see that the policy spells out a little more about, you know, change of tropism or enhancement.

DR. EDWIN: Thank you for that great comment. We'll take one more question. Then we're going to be 10 minutes over.

PUBLIC SPEAKER: Hi, everyone. Rebecca Caruso from Harvard. I want to thank my colleagues, Patty and Joe, for bringing up some important points about universities because we tend to face a lot of challenges regarding finance and funding which sometimes in private industry they don't have the same challenges. So I noticed on the panelists, only one of you actually mentioned you received two additional staff so I thought that was kind of interesting, and other people that have stood up today have also talked about having the same funding levels for their -- whether it's the biosafety program or their IBC, SO I'd be curious to hear in the afternoon session

more about funding and finance because it's come up a few times in our conversation this morning. Thank you.

DR. EDWIN: Thank you all for your participation and thank you to the panelists, and now I'll turn the time over to NIH.

(Applause.)

MR. BAYHA: So this is the lunch break now. There is a cafeteria that is kind of -- snakes around right where you came into the building. I think they have signs set up or there is definitely signs in the hallway that lead you to the cafeteria, or we could just have people that know where it is kind of lead the group there so that people don't get lost. That might be the easiest way to do it because like any good hospital, it's a maze in here. So I think I'll just stand up at the top of the steps and Chris, can you volunteer? Are you going to the cafeteria? You know, we'll lead the groups to the cafeteria just so you don't get completely turned around. If you know how to get there, please feel

free but we'll stand at the top just in case you're unfamiliar.

(Whereupon, off the record at 11:47 a.m., and back on the record at 1:04 p.m.)

MR. DIXON: Good afternoon, everybody. I'm going to stand up at the beginning just to get everybody's attention and let you know that yes, in fact, we are starting again. My name is Dennis Dixon and I'm from the NIH NIAD. My co-chair Joe Kozlovac is going to introduce the rest of the panel today, and we're each going to say just a little bit about why we're the people here and what connects us to this topic. And the topic is "Institutional Approaches to Developing Risk Management Plans."

So I've been with the NIH a bit over 20 years and in my branch, I won the prize of having many of the bacterial select agent pathogens and hence have a long history of federal interactions before they were select agents.

Also, I'm going to say that I actually

enjoyed serving on the federal committees that helped to frame the first two select agent rules as well as serving on the ISATAC Committee which is the Institutional Select Agent and Toxin Technical Advisory Group chaired by CDC and APHIS. And so with that background and also being associated with NSABB since the first meeting, I've had some experiences with these agents and can live to tell about them and still smile.

So I hope you all feel the same. We're all in this to preserve the integrity of the scientific process and to continue exploring research to the fullest in this important pathogens.

So I will stop there and turn it over to Joe who is in the federal sector just like me and he is at the ARS and U.S. Department of Agriculture and the Biosafety Officer there.

MR. KOZLOVAC: Thank you, Dennis. As Dennis mentioned, I'm the Agency Biological Safety Officer at the U.S. Department of Agriculture's Agricultural Research Service which is the in-

house research arm of USDA. You can read my bio so I'm not going to -- it was in everybody's packet so I'm not going to waste any time with that.

So I would like to introduce our panel. We have a very august panel for this specific session. Two are very old colleagues of mine, Dr. Joe Kanabrocki who I'll introduce first because he's up first, is no stranger to being here at NIH. He is a voting member of the NSABB. He was a former voting member of the NIH RAC. He also at one point was serving on the NBBTP program and was -- is the current NRCM Chair for ASM for the certification exam. Joe is currently the Associate Vice President for Research Safety and Professor of Microbiology at the University of Chicago. And in these capacities, he serves as the Select Agent Responsible Official, University Biosafety Officer, and Director of Biosafety programs at the University.

The individual that's next up is Rebecca Moritz. Rebecca is a biosafety and biosecurity

professional. She holds a bachelor of science in bacteriology, a master of science in medical microbiology. She currently serves in the University of Wisconsin in Madison where she is highly involved in select agents, dual use type programs.

And then third up is Mr. Phil Hauk water heaters o is at Mount Sinai. He is a biosafety professional with over 30 years' experience. He's also a medical microbiologist and has been involved in many of the American Biological Safety Association. You can also read his bio.

So with that and to save time on speaking, I'll ask Dr. Kanabrocki to come up and start this off.

DR. KANABROCKI: Well, good afternoon. I first want to say thanks for the invitation, for allowing me to participate here today. I'm pleased to be here. This is a very important discussion.

I'm here to talk about the risk mitigation strategies we're using at the

University of Chicago and before I begin, I wanted to just give you a little bit about the organization of the University because in my view, that impacts the governance structures we've established and I think these governance structures play a huge role in risk mitigation.

So first of all, we have two campuses. We have the Hyde Park Campus where the bulk of the research activity goes on and then we have the Howard Taylor Ricketts Lab which is a regional Biocontainment lab built through funding by NIAID. The nice part about the Ricketts Lab -- well, a lot of nice things about it -- it's a state-of-the art facility but it's located on the campus of Argon National Laboratories which is about 25 miles southwest of Chicago. Argonne is a closed campus. It has security guards up at the entrance and so heightened security at the Ricketts Lab is a given. So in addition to the campus security, we also have obviously security laid in at the level of the facility as well as the level of individual laboratories.

So when we talk about the select agent program, we're talking about the Ricketts Lab. Our entire select agent program is housed in the Ricketts Lab and, in fact, there are other pathogens that we work with in that lab that are not select agents.

But in terms of governance, because of the new laboratory, the University of Chicago decided to establish two IBC's, one for the Hyde Park Campus and the second for the Ricketts Lab. And the advantage for this is that all the folks who are in the select agent -- it used to be called the select agent IBC, it's now called the Ricketts Lab IBC -- they're very familiar with the facility. They're very familiar with the standard operating procedures of that facility, and they've been through the facility and understand what we do. We have things much more standardized in that context and so we find that our review process is much more -- it's much more expedited just because of the familiarity with the SOPs and the facility itself.

Now in terms of dual use review, we've created a task force that has membership from of the committee. And so we have membership from the Hyde Park committee. In fact, the chair of the Hyde Park committee sits on the task force as one of the regular members. And then the chair of the Ricketts Lab committee -- or the Ricketts Lab Select Agent Committee is also a member of the dual use task force.

As I mentioned earlier, we have the Director of University Research Administration as a member. We have representation from the veterinary staff. We have an attorney and so our dual use task force is really separate from either IBC. We do -- because we have the chairs of both IBCs on that task force, we do report out to the IBCs, the funding -- the findings of the dual use task force, but the deliberations of that task force are not part of the IBC meeting minutes. So in terms of structure, we've created a place where we can communicate to the IBC and provide a degree of transparency but at the same time, really get

into the nitty-gritty of it on the dual use deliberations.

So we have -- you know, again, we have finite number of PIs at the Ricketts Lab. We have basically six pathogens with which we work, five of which are select agents, two of which are tier one select agents and, therefore, subject to the review. Obviously, we also work with attenuated strains.

So first of all, the task force basically is involved in three functions. One is the initial review of grants before they go out the door. Second is continuing review and what we've done is we've synced up that continuing review with the annual progress report process that funding agencies usually require. So when a PI is writing a progress report, they're supposed to report to the task force about progress on the research.

And for the review, obviously, we first begin by asking those seven famous questions, but we also add an eighth question which really is

triggered by a yes answer to any of the first seven. And that eighth question reads, "does this potential outcome have an immediate threat to public health and security." Now what I want to say is in the realm of select agent, this is much more -- you know, that's a really difficult question but at the same time, we understand why it's being asked.

And at the end, I'll come back and just say that we've added those questions to our standard IBC registration process which is an electronic process. And so as you can imagine, when PIs are going through and registering their work and they talk about altered tropism, all the people that are using VSVG pseudo lentivirus are having to check "yes" there. But then when they down to question eight, "does it really threaten public health," the answer is "no" and so we're good to go.

But we're actually finding that those people that check "yes" to any of those first seven, those are folks we really want to talk to

about DURC and educate them. So we're trying to identify a subpopulation of our faculty who really need to know about DURC.

Okay. So now once we have a project that is DURC, how do we manage it? Obviously, in terms of manuscript review, there is a risk-benefit analysis and it's really could the research yield information that could be intentionally misused to threaten public health and safety or other aspects of national security. What is the nature of the threat that could be posed from intentional misapplication of the information? What are the potential consequences? Could the research yield information that could be potentially benefit the life sciences and/or public health and safety or other aspects of national security? And do the potential risks or publishing the research findings and conducting the proposed experiments outweigh the potential benefits?

So at the end of the day, it's a risk-benefit analysis and it's a very detailed analysis

and, you know, we really want to understand what are the real risks but really what are the benefits. And I think is really where I think maybe we need to work harder at articulating the benefits of the work we do. And I think -- you know, another thing I would say is that this process, it's a collaborative process. It involves -- at the University of Chicago, up until now, it was one that really began with the granting agency talking to the PI, the PI talking to the dual use task force and working in a collaborative effort to do the risk mitigation plan.

And now with the change in the way things are going to be going, obviously, it starts with the contact person for the dual use task force. And so we'll be the point of contact rather than the PI but up until now, we've been working through the PIs. And so again, in terms of grant review, it's a collaborative effort with the granting agency. We do an annual review in terms of progress reporting and then a manuscript

review is another thing that's done as a collaborative effort with the granting agency.

So what are the risks, the biosafety risks? We evaluate the potential for the trade of concern to evolve naturally. We consider the use of attenuated strains and use whenever and wherever possible. Obviously, we talk about appropriate containment and this is where knowing what the standard operating procedures of the Ricketts Lab are really comes in handy, fulltime PAPRS in our ABSL3 facility, etcetera. And then we talk about -- we look at the susceptibility to antimicrobial therapy and then making sure that the occupational health and medicine program and surveillance programs are very robust. And in this realm, we've developed agent profiles for all of our pathogens that will instruct a clinician on how a person exposed to that pathogen should be treated.

In the realm of biosecurity, obviously, there is physical security and as Phil mentioned earlier, I think one of the important aspects is

the inventory management. And so we have a very - - a really rigid process for management of our inventories. In terms of personnel reliability, we have a personnel reliability program that relies very heavily o a familiarity with our research staff and the use of what we have as a code of conduct document that everyone signs every year. And so that code of conduct is a commitment on the part of our investigators to take the training, to report any mishaps, to report observed mishaps that others don't report. And we found this to be very successful. People that sign their name on a document tend to take that document and what they're committing to much more seriously.

So again, as I said, you know, I think one of the things we really must work on is articulating the benefits of the research to society and public health. And again, thinking about the risks, obviously there are biosafety risks to the public health in the event of a release but I would argue that part of our job is

to explain to the public what steps we're taking to mitigate that risk and to argue that there is also a risk to public health for not doing that research. I think that needs to be more publicly communicated.

Also, there is a potential risk to national global security due to the publication of DURC findings. And in my view, we must insist that benefits outweigh the risk of work to be communicated and if that's not the case, I think we have to really think hard about whether that work should be published.

And then lastly, there is a risk to the loss in public confidence which I think we're seeing today. I think there is a lot of negative press around the work we're doing and I think it's had a real negative impact on the industry, not the least of which is that some investigators are either getting out of the business or students are not going into this area of research, and I think that is a shame.

So I think we must communicate in a very

responsible way that we consider and design our research with these risks in mind; that we mitigate the biosafety risk via experimental design and science-based biosafety programs; and that we educate the next generation of scientists to do this very important research. And I'll stop there. Thank you.

MR. KOZLOVAC: Rebecca, you're next up.

DR. MORITZ: Well, hello everyone. My name is Rebecca Moritz and I would like to thank NIH and OSTP for the invitation to speak today.

So the University of Wisconsin really views the review of potential dual use research and the risk assessment of that research as one in the same thing. It's very hard to do one or the other without incorporating the other essentially. So what is our process?

So our institutional review entity is actually a subcommittee of our IBC, like other institutions have talked about today. It is comprised of myself, the institutional contact for DURC, the IBC chair who is an associate professor

of virology, an associate professor of medicine who is also an infectious disease physician as well as conducts research himself, an associate scientist who is a virologist, and then the Director of the Communicable Disease Division of the Wisconsin State Laboratory or Hygiene which part of the CDC's laboratory response network.

So all the materials come into me, grants, manuscripts, experiments, and then we put them together and we all review them individually. We do our reviews on our own and we determine whether or not they meet the criteria of potential dual use. And then we come together as a group. And then we talk about our findings, and this allows us to form our opinions on our own, not be swayed by another individual. And then when we come together, we really assess the risks and the benefits of the research and whether or not we truly think it's dual use.

And I'll be honest. There have been multiple things that have come in that we have said, "yes, it technically meets the definition of

dual use but in all practical purposes, it's the cause of doing the science." Like for example, with influenza, to understand why something is pathogenic, you have to put in a low pathogenic strain to understand why that specific mutation has that effect. Technically, it meets the DURC regulations but is it truly dual use research of concern for example.

Now all of our findings are put together into a report goes to the IBC for discussion and review and then all of their comments and thoughts are put back into the report and it actually goes to a secondary committee, our biosecurity task force. Our biosecurity task force has been in effect at the University of Wisconsin for over a decade. It is comprised of a very unique set of individuals that under normal circumstances would most likely not be meeting together. So it's the responsible official and alternate responsible officials, the associate dean for research, biosafety officer, representatives from communications, our director of environmental

health and safety, university health services, information security and then we also have representation from legal, and then our sergeant and lieutenants which are in charge of the infrastructure security division of our police department as well as the deputy director o the communicable disease division of the Wisconsin State Laboratory of Hygiene who is also a select agent PI as well as the direct of the Wisconsin Veterinary Diagnostic Laboratory.

We're kind of a unique setup in the world of diagnostic laboratories because both of those laboratories, while they are divisions of the State of Wisconsin, they actually have agreements and are on the campus of the University of Wisconsin so they use our IBCs, they use our IACUCs, they use our IRBs, so that's a really great resource that we have.

Now like I said, under normal circumstances, these individuals would most likely not be meeting together but the reason we have this committee in place is really because

everybody in this group has a vested interest in the safety, security and risk mitigation of research with high consequence, pathogens at the University of Wisconsin.

So what type of risk mitigation measures do we think about when we develop a risk mitigation plan? Well, for example, let's talk facilities. Is there anything unique about your facility? What type of redundancies do you have? Is your building monitored by a building automation system? Do you have -- what biosafety level do you work at? Are you maybe working at a biosafety level higher than what the regulations say you necessarily need to be working at?

I really think most of your institutions are already doing most of the things that would be required to do for risk mitigation plans because they're part of BMBL, they're part of the select agent regulations, or they're part of the NIH guidelines. But really, the development of a risk mitigation plan puts it all into one specific place.

Another thing we ask ourselves is who is conducting these experiments. Is it graduate students? Is it post docs? Or is it scientists with 20 plus years of experience? What type of experiments are they doing? Is there a way to use attenuated strains or to try something different first?

We have had instances where we have asked for the results of an experiment before we have allowed researchers to go on and do the next step of experiments because we wanted to see what that data was before we let them go further.

What about personal protective equipment? Are you using respirators? What type, N95s, N100s, or are you using PAPRS, tiebacks, shower out? There are a lot of different enhancements that you could use there.

Have your researchers received the appropriate vaccine? Is there a vaccine available for the bugs that they're working with and have your researchers received it? Are the bugs your researchers are working with sensitive to

available antibiotics or antivirals? Do you have -- can your infectious disease physicians or your public health get you those if you need them in case of a potential exposure?

What are your quarantine policies? Do you have a personal quarantine policy? Do you have an avian policy? What is your exposure control plan? How good is your relationship with your public health authorities, the state, the local? What about your physicians?

Also, security. I had to give a shout-out to our security department there and some of our canine officers that they work with. The real tone in the middle, actually, I work with very regularly all the time. But, you know, how often do they do patrols of your facility? What is their response time to various alarms? Have they been involved with doing emergency drills or responding to scenario incidents in regards to these agents?

Also, what type of regular research updates are you receiving from your researchers,

because all of this really does stem on communication and the importance of communication? Now the University of Wisconsin, like many of you in this room, is a public research institution, and we do not view research to be complete until it is appropriately communicated to the public. So that brings up a really interesting question when you're dealing with potential dual use; you know, especially every single manuscript is different. So what type of questions do we ask ourselves when we are doing the review risk assessment of potential dual use research? And as Joe said, what are the benefits and risks of publication? That's absolutely important. Do the benefits outweigh the risks of publishing the material. Also, what is the value of research to science, to the specific science field and then also to public health. Will it be useful to public health? Will the public actually see a benefit from this research.

And then what about, you know, the biosafety and biosecurity measures that we use?

All DURC manuscripts that come out of the University of Wisconsin have a description of the biosafety measures that were used to conduct that research as well as what we can say publicly about the biosecurity measures that we have put into place.

And then what about media talking points and press releases? Now this is where that biosecurity task force I talked about is incredibly important because we have this breadth of individuals and experiences that we can bring when we create talking points. And our relationship with our communications department is absolutely critical because they help us frame our message. They help us put press releases together. They help field requests that come in for media because really, doing all of that work tries to prevent the sensationalism of a lot of what we do. And unfortunately, right now, there has been a lot of, as Dr. Kanabrocki said, there's a lot of press, there are a lot of things going on in regards to this field. And the more responsible

we are when we communicate about it hopefully we'll lessen the risks of that happening.

But I just want to end with saying, you know, I think a risk mitigation plan really describes everything an entity is doing to mitigates risks but it puts it all into one place instead of, you know, your IBC has this, your -- you know, your IACUCs have this, your select agent people have this. It really puts it all into one high-level plan for people to see what you are doing to mitigate risks at your institution. Thank you.

MR. KOZLOVAC: Thank you, Rebecca. Phil Hauck, you're up.

MR. HAUCK: Okay, that's who I am. And we've beat this to death but just in case you want to know what the seven outcomes are that we're looking for, there you go. And what I'm going to actually do is walk you through a mitigation that we did back in 2012. We took a look at the research and that's our questionnaire that we developed, some more of it. By the way, you can

always email me for the slides. I'll get them to you.

So this is Dr. XYZ. You know where I work so you can figure out who one of three possible researchers it could be but this is exactly what they were looking at, host-specific functions of -- of course, H5N1, as an organism that's near and dear to three of the panelists here, okay, for obvious reasons. It started the whole DURC thing going. And basically, you can see he said, "Yes." So you know it's a "he." And basically what we were looking at was this particular polymerase that they wanted to work with and the HLRA mutant. So we go to the next and the bottom line is the bottom line. I don't read slides. So basically you see what was of interest to us and what they were looking at specifically in this example.

You got to the next slide and again, what are we looking at? What is the potential to either increase or decrease? We see that the researcher said that. We would be actually

decreasing rather than increasing virulence or transmission because of the type of strain that we're using. And again, everything that's "bold" is what stuck out in my mind when I did the original review of the document, and what they're primarily interested in was the polymerase complex and how that could activate innate immune systems. So basically, you're working with the attenuated version of the HALO virus and basically they realize that they could get the same bang for their buck out of the HALO as they could working with the full pathogenic because what they were interested in was the intact polymerase complex.

And again, the other variants were not able to do this. What they were interested in is the ability of the HPAI viruses to transmit between species or the roles of HA in transmission. And these are not being studied, okay, in this particular case, but what they're more interested in was just with the polymerase. And as they noted it indeed was critical to do this and we agreed with them when we did the

overview, we did the risk assessment.

And the key line here is that the molecular mechanisms are still unclear so that's the reason why we're doing this research. It's not willy-nilly and I just want to know the information for the sake of knowing. And basically, they're trying to work out a system where it could find novel drug targets, understand the host virus interactions and understand how jumping occurs between birds and mammals.

Their contention was there are no direct DURCs associated with the research project. And we said, "Yeah, on the basis of what you've presented, we agree." Research will not change the tropism beyond that which has already occurred in nature; we kind of agreed with that. We like that. That was very reassuring. And then again, as you can see in the "bold," polymerase from the A/Vietnam virus or similar H5N1/HPAI virus must be used in the experiments. If you're going to try and understand what's going on there, you have to use those because the other strains are divergent

and they are not true with that H5N1 polymerase so you have to go to something that actually has what you're looking for.

So we didn't need to use intact wild type HPAI in the research and basically, we looked over and said, "Yeah, it looks okay for now." And since the viruses are attenuated, dual use is not a high risk. Now note, I like the way he said that. It's not a high risk. There's always a risk when you do the experiment. You may come in one day and find all the mice dead in the bottom of the cage. That did happen in one of their experiments but we found out that it was an artifact. They didn't clean up their injectable agent, and we found out there was something else in there that inflamed the mice and killed them all. It had nothing to do with the virus. So, you have to be careful when they report back to you "oh, we killed everything." Okay, that's not good. Tell me why this happened, okay. Because you didn't clean up your stocks properly, you got a pyogenic effect. Okay, that makes sense.

All right. What we also liked was that they realized they work in a BSL3 lab. They're all SEGIS (ph) cleared. They're all SRA approved to go in there and we, you know, stand on them constantly making sure that they're inventories are correct at all times, that nothing is missing or underreported or overreported, as the case may be. Sometimes you find that stocks are there that are no longer in the boxes but they're on the sheet. That could be problematic but it also many, many vials and not enough sections on the inventory sheet complete could be also problematic.

So we deemed the results could be reported out, you know, based on getting reviewed from NSABB. We sent our findings when we did the review to the NIH who is our funding agency, but we also sent along to the NSABB -- they kind of wanted to know anyhow because it was H5N1; this is back in 2012 and they agreed with us that there was nothing problematic in publishing it so it went published and life is good.

And the bottom line here is, as I said before, we decided that we have a separate committee now which we call IDUC. And I told that joke before. I won't tell you again. But basically, it's a separate committee. It's advisory to the IBC and also reports to the BSL3 oversight committee, our findings, so there is a little tangled web there, different internal regulatory agencies are watching what's going on. So researchers are not running amuck in the lab or if they are, we'll know about it real quick. Thank you.

(Applause.)

DR. DIXON: In the interest of time, I'd like to give the audience the opportunity to have access to the minds here who have considerable experience with DURC. It's a nice opportunity for any of you out there to ask questions or share experiences or so forth, so if you do have a question, please come to the microphone at either side and have at it.

PUBLIC SPEAKER: Rebecca, you addressed

information technology security a little bit because one of their -- or maybe more than one -- representative is on your biosecurity task force, but I'd like to get a feel from those of you at universities, because that's all three of you, how you do intend to address that. We had one comment or question about that earlier today and we've talked a lot about physical security and those kinds of things. We haven't said much about information security.

MS. MORITZ: Sure. So being form the University of Wisconsin, we have a little bit of experience of having a manuscript that people want to get their hands on but it cannot be seen by the public. So back in 2011-2012, we started to think about, from an information security perspective, where we were vulnerable and we actually brought in an information security consultant to take a look at the way our select agent program is set up.

We have seven select agent laboratories and they are in various schools and colleges so

they were all served by different IT departments. So what we decided to do was actually centralize them and put built in controls that we can guaranty that we're meeting the requirements of the select agent program. But I can tell you this is incredibly expensive. It's not cheap. And we are in the process of giving researchers encrypted laptops but this is, again, not cheap. And especially under the current funding restraints in the State of Wisconsin, it's making things very difficult right now but it is absolutely something we've thought about and considered.

DR. DIXON: Organizer colleagues, if we have provision for web-based questions, I think we are accepting those and if so, do we have any? We are looking. We do have that provision. We are so pleased that this is so clear to everyone.

PUBLIC SPEAKER: (Inaudible.)

DR. DIXON: Good. At least we know people are listening or trying to listen.

PUBLIC SPEAKER: I think it's just like that, I'd want people to go to the microphone.

DR. DIXON: Another question over here on the side of the room.

PUBLIC SPEAKER: Hi. So a couple of you alluded to the issue of sort of public trust and how that kind of relates to transparency of this process and that we maybe need to do a better job of communicating the fact that this risk assessment is done and it's very thorough. Do you guys have any comments about what parts of this process -- because obviously a lot of it has to be confidential because of the same security issues of publishing the results of the research -- is there any kind of thought about, you know, what parts of this process can be made publicly available or if maybe some kind of, you know, statute of limitations, maybe these processes five years later can be sort of released or some part of them so that people can kind of see, the general public can see how this review process works and what kinds of things it's able to account for?

DR. KANABROCKI: So I think the punch

line in the risk-benefit analysis -- so you can articulate the risks and you can articulate the benefits without really getting into hard data, and I think that's totally fair game. That should be totally fair game and I think that's what the public is interested in.

DR. DIXON: Question on the opposite side of the room.

PUBLIC SPEAKER: Yes. Gary Sherman, USDA, NIFA. I'm curious about the tie that you all think is appropriate to produce a risk mitigation plan and how that relates to the length of time that you think is appropriate to do the risk assessment that would have to proceed that and relate that, if you can, to those who are proposing to federal funding agencies that timeline?

DR. KANABROCKI: So our process begins with the PI and their assessment and obviously they're motivated so they do that promptly. Then it goes to the task force and we basically take -- I mean we try to get -- once we've received a

request, we try to get it down within two weeks and then we can communicate to the granting agency and they've been very good about, at least in terms of publication, they've been very good about responding in a five-day timeline. So I mean if you're ready to publish, it doesn't really -- I'm sure you guys had a different experience over here but needless to say -- but it's been pretty smooth for us. And then the upfront reviews, similarly; you know, the PIs that complain one day is too long of a wait, but I don't know that a month even is that bad. Rebecca?

MS. MORITZ: I would agree with Joe. It really depends upon the PI notifying you and once you're notified, depending upon where that kind of falls in our cycle because our DURC subcommittee meets a specific time each month; our IBC meets two weeks after that; our biosecurity task force meets a week after that, so if they meet that initial deadline so to speak or they can't -- they don't get something to us before that subcommittee meeting, then they're going to have to wait unless

there is some sort of contingency on the information for a granting agency and we have a heard deadline that we need to meet. Then we can move things around a little bit.

MR. HAUCK: I'm fortunate the number of people that I deal with that are actually working with agents that could be DURC related that they already have the idea in mind that once they get the idea to do the research with that particular agent, that they're immediately reaching out to myself and also the chair of the IDUC committee, also chair of the IBC, because they know they're going to have to get the approvals up front. So before it even goes into, you know, the formal grant process, we're already looking at it so we're ready. Hopefully, we have information that it can go almost instantaneously once I get notification about acceptance of the grant.

DR. DIXON: I see we have one more question in the room but before going to Chris Viggianni, I just want to ask each of you how do you identify the denominator for determining

whether or not you have DURC involved? Are you solely dependent upon the PI to self-identify?

MS. MORITZ: Our IBC has also identified things that have shown up in IBC protocols and have actually sent things back to the DURC subcommittee or, for example, they've even sent experiments -- we've had a handful of experiments they have said that are actually not one of the 15 agents, that the IBC identifies.

DR. KANABROCKI: Yeah. I mean for the current policy it's limited to the tier one select agents plus the two viruses and so we -- it's a captive audience. We know who our PIs are.

MR. HAUCK: I'm kind of the biosafety/biosecurity cop on watch which means I'm on the IACUC Committee, I'm on the IBC Committee, and I am an ex officio member of the IRB, and I sit on the Escrow Committee so very little escapes my watchful eyes. That's not to say it doesn't but the thing is that we're out there looking and I'm constantly looking for somebody working with 1 to 15 or something that could be -- you know,

looking at that research, the descriptions. And if I have a question, I reach out to the individual and say, "What are you doing with the agent?"

MS. MORITZ: But that does bring up the point of below threshold levels of botulinum toxin which are concluded I these guidelines and that is a lot more difficult because you're basically relying the biosafety protocols to find who those individuals are and you have to hope and cross your fingers that they have it in their biosafety protocol. That's where the catch is going to be and it's going to be a lot harder to find.

MR. HAUCK: Well, we really narrowed it down to the neurologists and the gastroenterologists because they're using Botox, and we're also going to send out a survey saying "you playing with any other of the toxins as well as the Botox," so we're not singling out just the Botox crowd. We want to know who's working with what the institution.

DR. DIXON: Chris.

PUBLIC SPEAKER: So I wonder if -- are there any examples where you've looked into various risk mitigation measures and the only thing you've been able to settle on is to either significantly alter the experiment, do it in a fundamentally different way or to not do it at all? Have you ever run across those instances and if so, can you tell us a little bit about them?

DR. KANABROCKI: I'm happy to say I haven't read into that at University of Chicago yet but again, I do -- I mean I think that at least in terms of publication, if you have a finding that you can't argue in an intelligent way that the benefits outweigh the risks, you really have to wonder about that publication and whether it should go forward.

MR. HAUCK: I showed you one example before. Most of our research is being done in attenuated models. Again, the researchers are very aware of what they're working with and again, they don't want to get infected with it and they don't want anybody else getting infected with it,

so I'm blessed.

DR. KANABROCKI: Just one more comment there. I think, you know, as we all probably feel, we have 15 pathogens or 15 agents on the list but as we've seen and as we know, DURC isn't limited to those agents. And so we are trying to cast a wider net and educate the community about DURC even if they're not working with one of those 15 pathogens. But, you know, obviously, some of the classic cases of DURC don't involve one of those 15 pathogens. So I think we really have to ask that really hard question, what is the end game and where are we going. At the end of the day, is it going to stay limited to those pathogens or -- and, you know, this goes to this whole issue of lists which has been debated for many years.

DR. DIXON: So we're near the end of our time and yet I wanted to round out with one final thought that I thought was interesting as we were going through preparation for this panel on the phone. And I think we all recognize that we found

ourselves in a new place needing to do these kinds of assessments and we started with how do we do this, what makes sense. I suspect there are people out there who want to know how do we know if we're doing the right thing for the risk mitigation plan, what are they looking for, what should it look like, will they know it when they see it.

And so I think it was pointed out a couple of times throughout the day that we're not starting from nowhere in terms of risk mitigation plans and that -- I don't know of any instances where we're not dealing with a select agent. And so the select agent rule is in law and there are specific explicit ways to do the risk assessment/risk mitigation plan or at least conceptually that people develop these explicit protocols.

So would any one of you like to summarize our discussion on what you see as being different from DURC relative to a select agent risk assessment plant/risk mitigation plan?

MS. MORITZ: Communication of the research.

DR. KANABROCKI: Yeah. So I think that's an important fact to consider. A select agent is still a select agent unless perhaps you make it a worse select agent in which case why is it worse and does that invoke new risks that you need to test for. But I think the communication aspect is really important and in the companion guide, there's a long section on that and I would imagine -- I know the folks in the government are happy to help guide you to the right place and I imagine there are colleagues in the community who would be happy to share your experiences with those who find themselves in that situation.

DR. KANABROCKI: I would add one more thing. I think it's largely about communication. I shook my head vigorously when Rebecca said communication and I really think that's the bulk of it. But I also think that it is forcing all of us, the PIs, the folks that help with the work, and those that fund the work to really think hard

about how to do responsible science and to ask that hard question, "Should this experiment really be done and what's the gain?" I don't know that that's necessarily being asked without this. I don't think select agent gets you there so that's another piece that I think is added to the process.

DR. DIXON: I don't see (inaudible) they charging to the microphone? We're at time so I think we'll stop here and go to the next item on the program.

(Applause.)

MR. BAYHA: So afternoon, everyone. My name is Ryan Bayha. I'm the Senior Analyst for Biosecurity and Biosafety Policy here at the National Institutes of Health. Before we get into this presentation about outreach and education on the dual use research issue, I just wanted to echo Susan and Carrie's welcome to everybody that's at the webcast and to the people in the audience, a special welcome as well because we do realize travel budgets are very tight to get here. We

realize Washington, in the idle of July, is not a particularly destination due to the heat. We also realize that it's not a very easy facility to get into sometimes. So we do appreciate your determination in getting in here and I think it's a real testament to your dedication to your jobs that you showed up here, so we thank you for that.

I think one of the themes that we've seen so far in the meeting is, as Joe and Rebecca and Phil mentioned, there is this kind of public notion that this research is very dangerous and that it's unchecked and there's nothing standing in the way between this research, you know, for lack of a better term, you know -- I won't even say it but But really, I think this is really a good message for why institutions should strive to be as transparent as they can because I think the mere fact that we have, I think at last count, nearly 200 people -- 200-plus that are just either attending in person or watching over the webcast. This meeting shows how many people are actually dedicated and care about this issue of making sure

this vital research is done safely. So I think if institutions strive for transparency, that might make the public a little less worried about what's going on if they knew how many talented people were actually keeping them safe.

So with that, I'll actually start my presentation and the purpose of this presentation is really just to give you the landscape of what the outreach and educational materials that are available are. So some of it will focus on what we've done here at NIH and some will focus on what the USG materials are. It really doesn't matter whether it's an NIH or a USG material. They're all available to you for your use.

So the goals of outreach and education for dual use research of concern, we really want to promote general awareness of the issue among the scientific community and other stakeholders, apprise the research community on the status of the federal policy-making process. We want to promote and engage thoughtful input from stakeholders on the NSABB's work products and

federal policies, and we want to sustain a culture of responsibility. My presentation will focus really on the first three items here and the ways that we accomplish and achieve those goals.

So general education and awareness-raising, how do we really go about doing it? It's a big task. One of the major ways we do this is we have exhibits and posters at major scientific meetings and conferences. At NIH, we're usually at a lot of the major biosafety conferences so we either pair it with something we're doing at a biosafety conference or we might just do a biosecurity exhibit alone on dual use research.

This is a screenshot of our lovely booth. It's very "blue." It takes three union personnel about 3-1/2 hours to put it together at a conference so it's a very involved process but it's very colorful and it draws a lot of attention. We get a lot of good traffic at conferences. The three most important things in this picture are the red bins which usually have candy and draw people to the booth. Most of the

time, my colleague, Kathryn Harris, is putting the candy in there out of her own pocket due to prohibitions of government spending money on these type of things. So I just wanted to thank Kathryn for providing that candy to the public.

You can see on the table we have a number of different outreach and education materials, whether they be NSABB reports, FAQS. You can see kind of that green brochure there which is also in your packet. That's the general dual use brochure. And we also have a multimedia exhibit where we have a slideshow going on TV in the background that can either portray a few slides about dual use research or about biosecurity in general.

This is an early poster we used to exhibit. It was really just an introduction to the biosecurity issue and an introduction to the NSABB. It pretty much went over what dual use research is, who the NSABB are and what their main functions would be. Yet another early kind of iteration, we meant more from an NSABB poster into

the dual use research and the life sciences poster. Again, it just really is a primer on the issue. It wasn't meant to be exhaustive but it was really just in the early days to get people thinking about this issue and having it on their radar screen.

This is actually our latest iteration and I think this is a very good educational poster. This is obviously a poster so it was too big to put into your packets but if you want copies of this poster for your institutions, just email and we'll send you as many as you need. The purpose of this poster -- now some of you might be familiar with our recombinant DNA poster. We had a poster that said, Are You Working with Research Involving Recombinant DNA? If yes, contact your biosafety officer because you might be subject to the NIH guidelines. You know, you have to register with the IBC. This poster was kind of borne out of the same principle. Many times as well, when you mention training to investigators, you automatically assume it's a PowerPoint, it's a

classroom presentation, but this is actually a very effective and quick training presentation to a potential PI if it's put in an area where PIs congregate or they're frequently seen. It's very eye-catching just due to the colors and the graphics. It asks very simply if your research is involving any of these 15 agents; if yes, you might want to contact this institutional contact at your institution to see if your subject to the DURC policy. It doesn't attempt to give you the entire presentation in one lump sum or in one sitting but it really just gets an investigator thinking about these issues, whether they might be subject to the policy, and if they have questions, who they can actually contact for more information. So I think this is very effective and again, if you need co pies for your institution, we have tons of them. We'll be happy to provide them upon request.

We also utilize a lot of multimedia educational materials. Some of you may remember that about in 2008, NIH put together an

educational video intended to be an awareness-building tool that can serve really as the opening chapter for future educational materials and for a dialogue at your institution. The video was a conceptual introduction to the dual use issue. It's interesting to note that really it's more focused on DUR rather DURC because it was in 2008. The video also features nationally- respected scientists and policy-makers describing the relevance and their importance of the issue, so people like Maxine Singer and Eckard Wimmer are featured in the video and it's a very good introduction. If you have people on your staff or people that might not be familiar at all of what the dual use research issue is, it's a very good introduction to get them thinking about it. It is available on YouTube. I think the last time I checked, it had about 13,000 hits so that's not too bad. It'll never get to the level of, you know, the cat following the laser pointer kind of thing but it's been pretty successful so we're pretty happy with the amount of people that are

watching it. I think we do still have some CD copies available if you want to request them but I think this is a very good resource as a beginning primer in the dual use research issue.

This brochure is in your packet. It was an earlier iteration that we started that just, again, it was the general issue, "Does your research have dual use potential?" It was targeted specifically to investigators. Much like the video, it offers a conceptual introduction to the issue. It is available on both the S3 website and our NIH website in a pdf form. Also, if you need more copies to hand out to your investigators, again, just drop us an email and we'll provide to you as many as you need. We've already distributed 5,000 of these brochures to institutions. I think we began printing these maybe two to three years ago and so 5,000 we have already distributed. And again, we have a lot of them so we encourage you that if you need these brochures to get in touch with us and we'll get you as many as you need.

This is another good kind of training activity. It's not a classroom. It's now a PowerPoint presentation. This is a simple PI responsibility brochure. It's targeted again specifically to the PI community, available in print and electronic form, and I think we've had roughly about 3,000 to 5,000 of these already distributed. You'll find a copy of this in your packet as well. Again, if you need more copies, we are definitely available to give you more. This is a good tool because if, say, a biosafety officer or someone in EHS or someone in the select agent program, they can just take this procure with them when they're going to the lab to talk to a PI and they can actually just very quickly go over it with them, their responsibilities under the policy. It's not a very labor-intensive process. You can go into the lab. You can just kind of have a collegial conversation with the investigator and say this is a brochure that the government has put out. These detail you're responsibilities. You know, we're obligated to

train you on these. This is just one thing we're going to do to help you understand what you have to do under this policy.

We make many presentations to key constituency groups on the dual use research issue, on NSABB activities, and federal policy-making as well. We have also prepared standard slide set for training purposes. This is on the S3 website. This slide set, I think there are about 50 slides. It's a general slide deck. Fifty is probably much more than any one institution would or should ever need. However, the point of the slide set was that you could take it, you could keep the slides you want, you could throw out the slides you don't need, and whatever slides were specific to your institutional purposes, you would just insert in. So what we were trying to achieve here is that you didn't have to start from scratch with how am I going to do an entire dual use research of concern training slide set. We've kind of done that for you. So this is on the S3 website. We encourage you all

to take a look at it, provide any feedback on it that you have and use it as you need and augment it as necessary for your own purposes.

Another thing that we specifically do here at NIH is that some of you might know, our "IBC Basics" and our "Effective IBC" course, Kathryn Harris and myself usually teach these probably three to four times a year. This is really for the IBCs and their responsibilities under the NIH guidelines. But for the past several years, probably the past five years, we've been incrementally increasing more information in those sessions about dual use research of concern and about the dual use issue. So we used to have maybe a 20-minute presentation. Now I think we generally can split it up to either a half a day on the IBC requirements, maybe half a day on the DURC requirements. And we have slides that ago along with this presentation so again, if you want those, please feel free to ask us for them.

Another aim and mode of outreach is to keep the community current on the status of

federal policy- making including the activities of the NSABB. I think the importance of the NSABB has already been well- established just not only today but just through their existence. But the main way we keep the public informed of these activities are our website. It's the portal for all information on the NSABB. It's meetings. It's work products. There is an email inbox for public queries. If they have questions about NSABB deliberations or NSABB meetings or NSABB products, the pubic, at any time, can email to the NSABB inbox to get their questions answered. And also, the Office of Biotechnology has a listserve where we periodically provide updates that are of importance to the research community.

This is just a screenshot of our biosecurity webpage. You'll notice that it has two subtopics; one is dual use research of concern. That's where you would find all of the resources I have been speaking about today. And then the second one is the National Science Advisory Board for Biosecurity, so that really is

all the information we have about the NSABB. That's the roster, their charge, information about past meetings, all of their past meetings are online there, information about future meetings, and just any other information you would want to know about the NSABB is all right there on our web page.

Another thing we do is we also have a job of disseminating the NSABB work products and the information. We've all talked about NSABB's important role in the policy-making process. IT is a vital job to disseminate that work, those products, and the information so that the public can kind of know where these policies are coming from, that they just weren't created in a vacuum, that these policies actually were rigorously thought out and vetted and then made into government policies. This is just a screenshot of what the NSABB reports.

Kind of the fan out look on them. I believe it's current with the seven reports. It might be more but this is just to get you just

visually attuned to the type of work products the NSABB has produced. Again, all of these are on our website.

Another thing on our website are general biosecurity FAQS. So we have FAQS about, you know, what's the NSABB, what's biosecurity, what's DURC. And to match that, we also now have institutional policy-specific FAQS so these were designed specifically about the institutional policy. I believe there are 15 FAQS now on this list. It provides information about institutional representatives and it also tells you where you can find more information or additional guidance or resources. This is a living document. I think one of the major things that this meeting is going to probably provide is more frequently asked questions to this document. So since we've had a lot of good questions here, we're probably going to want to amend these to reflect some of the questions we've heard. So I would not be surprised to see this document amended. Right now, of course, with all the other documents, it's on the

S3 website and it should be a good resource when you're implementing this policy.

We also do outreach through blogs, articles and statements. I would be remiss if I didn't mention our own blog, our new Office of Science Policy blog. Several of you, or based on the numbers of subscribers we have, maybe many of you probably got the last message about Carrie Wolinetz' invitation to the DURC workshop, this is going to be a very exciting blog. It's interactive. It's not just going to be about biosecurity but it's science policy issues in general, but I'm sure biosecurity will be a hot topic in the blog. Right below there is the link where you can subscribe to the blog and you can also get to it from our web page as well.

We've also issued, in the past, statements, articles, and various other policy documents. There have been statements from Dr. Collins that have been posted to the IH Directors page. There have been published articles about extra oversight and things like that, so there

have been numerous forums that we've used.

So we get to the point where ensuring stakeholder input into NSABB work products and federal policy-making is now the topic. So we do this through two main ways, the Federal Register notice which makes you aware that we're going to have either a public consultation meeting or a meeting of the NSABB. That's very important because it shows that, you know, it's a transparent process. The NSABB meetings are announced in the Federal Register. The public is invited to attend. All of the materials that are presented at the meeting, provided they're not security-sensitive, are then posted on the website for the public to review.

Public consultation meetings like this one are of a lot of importance to the policy. I don't think it can really be understated. I think we've heard of two issues so far that really we wanted to hear -- so the Botox issue about the under the minimum quantity and the difficulties, these are things that we really need to know about

because the policy is still kind of in its nascent phases. It's alive but it hasn't really been implemented yet and there's not a lot of experience in implementing it yet. So things like the Botox issue and things like the scope of the policy, like the 15 agents, there was a particular reason why it was limited to that scope, because when you're first putting that policy into place, you don't want to be overly burdensome and say, okay, it's going to be 35 agents and everybody's got to gear up this and I think even the policy acknowledges that those 15 agents are not the universe of potential DURC but they're just the highest potential right now with our current understanding. So that's why that scope was limited like that.

However, the comments that you provide are what helps us eventually amend these policies, so we do want to hear your thoughts on the scope of the policies. We do want to hear your thoughts on Botox being, in any quantity, what type of burden that poses or whether we're really meeting

our goal of managing the potential risks without slowing down the research. So we do want to hear your opinions on this and this is a great form for it and, of course, like Carrie said, this is not your only bite at the apple. There are multiple opportunities to keep engaging with us on this topic after this meeting ends.

So here's the groan. Everybody sees the policy. It's up there. It was issued September 24, 2014. It's effective September 24, 2015. Institutions had one year. We're down to about two months now where before you have to implement and have all your oversight systems in place. And the reason we gave that year was we determined that that would be a sufficient interval for appropriate education and training to take place. So, really, the tools and resources listed below on this slide, the purpose them is to help identify and comply with the DURC policy, how to perform risk assessments and develop and risk mitigation plans, and how to responsibly communicate the findings of DURC research, and

those tools and resources all further those goals.

So I'm going to spend the last few minutes of the talk here just talking about some of those resources. The companion guide, which is in your packet, I think would probably be your most important resource when you're implementing this policy. The policy itself is about 13 pages. The companion is 85. It's a typical government thing where the policy is two pages and the implementation is 172 but it's a very important resource. I think most of the general questions you would have probably could be answered by taking a look through the companion guide. It has a lot of information on how to conduct a risk-benefit assessment, responsible communication strategies. The appendix of this document actually has some template forms for how to report in DURC information to the USG if you wanted to use that template. So I just think there is a lot of great information here. There's also a series of FAQS included. My advice would be anytime you have a first question that pops into your mind,

the first place you should probably want to go is the companion guide and obviously, if the companion guide can't provide you with the answer you need, then to contact us. But I think this is really going to be a lot of institutions' best friend in implementing and continual compliance with the policy. As I said, it's got FAQS. It has a lot of guidance for PIs, guidance for IREs. And the templates, again, sometimes this is helpful where if institutions don't want to kind of create their own templates from scratch. The templates are kind of nice because they kind of give you the baseline information the USG would be expecting when you're sending something to them to you don't have to kind of guess, you know, would they want this type of information, is this extraneous, so the templates are kind of a nice start. Feel free to, obviously, augment them to your own institutional purposes but it's a good start for these.

Case studies, I think it's a universality that everyone likes case studies or

everybody wants case studies. These are some case studies that were put together I think about a year ago. The provide a range of examples of research that are subject to the policy. And really, the point of these -- and these are very short case studies -- they demonstrate the types of analysis that should be brought to bear during IRE reviews. So these case studies are not going to be like the one that we all went through this morning. These are much shorter and just kind of give you the kind of three or four basic things you need to think about when you're reviewing a protocol like this. So this case study, which I mean, this was trying to be more of an exemplar where you could apply the knowledge you use in this case study to almost any situation involving DURC. These are specific examples of DURC and the type of analysis that should be used on those specific examples. So they're complementary but they have a little bit of a different function.

For this case study which Marci did a fantastic job on presenting, I think this would be

a good tool for the IRE to go over with their committee. Obviously, it's pretty lengthy. You might want to chop it down, take off the parts you don't really need too much but just it's a good training tool I think. And again, it gets away from the traditional PowerPoint classroom training and it's something a little bit more interactive and maybe even a little bit more engaging. You could amend this to your own procedures and you don't even have to do the whole thing in one sitting. One meeting can be part one or, you know, you can just focus on the risk communication aspects of it if you wanted to. But I think this would be a good training tool and I think also the slides that Marci had up here to accompany the case studies, I think that would actually be a good tool for future moderators of that case study to actually study so that they know how to present the case. So I think that could be a valuable tool as well and have it actually present the materials because it's very involved.

So future outreach and education on the

institutional policy, we've kicked around the idea of possibly having some webinar-type training for ICDURs and others so that everybody can be on the same page about what their responsibilities are under the policy. We at NIH plan on continuing our presence at key society and association meetings. We can usually be found at ABSA or meetings between AAU and COGR, ASM, FASAB, and a number of other scientific societies.

The last few slides I want to go over are international engagement slides. I think it's been said earlier that this is not just a U.S. issue, this is actually a global issue so I think we'd be remiss not to go over some of the engagement we've done with the international community on dual use research. So the objectives of the international engagement has been to raise awareness of dual use life sciences research internationally, gain a global perspective on DURC issues and conflicts of interest to the USG, create an international network of individuals and organizations who are interested or engaged in

these activities; I mean a good example is the French delegation who I had the pleasure of meeting at lunch, that's a result of our international engagement, and also just maintain aware of the global status of activities that are relating to DURC and identify any progress or gaps that we see.

We've accomplished international engagement through a number of different methods, international roundtables, interactive webcasts, video-telecons, and international workshops. I won't go through all of these but we've engaged a lot of inter-governmental agent organizations, philanthropic organizations, industry. Here's just a quick shot of all the NGOs. So it's been a pretty exhaustive process. We have partnered with WHO. They've co-sponsored two international roundtables where WHO experts presented at two regional events. They put out this 2010 WHO guidance document that you see, and there was also an informal consultation on DURC in February of 2013.

So the impact is we've identified individuals or countries or organizations who are active or have similar interests in DURC. We know a lot better now about the current status of DURC activities and management strategies on a more global basis. We've created an international DURC network and we have a collection of archived educational resources that can be broadly used by governments, institutions, or policy-makers. And also, it just contributes overall to the general policy discussion and the oversight when we have kind of the perspective of other countries in mind as well when we're making these kind of policy decisions so that's been very helpful for us.

This s just a map to show you the regions that have been engaged through the international outreach, just kind of gives you a sense of where we've been targeting and who's been receptive to it and kind of the gaps that are left.

So any additional information, the one-stop shop for this will be the S3 website. It has

all the information about dual use research in the life sciences. It gives specific details on all the policies. If you wanted to see the March 2012 policy which applied to government agencies or if you want to look at the institutional policy, it is up on the S3 website as well and you can find that web link right there. I might actually leave that up in case there are any -- yeah, I'll just leave this up while we do the questions.

Are there any questions or comments about our outreach efforts or We also want to hear about what potential outreach materials would be helpful to institutions as they implement the policy. We don't intend for this to be the entire universe of our outreach. We really do want to hear from you on what would be helpful and what would help you implement the policy.

PUBLIC SPEAKER: So Ryan, I want to thank you for that presentation and just mention to the folks in this room, if you don't already know it, Ryan actually answers his phone.

(Laughter.

PUBLIC SPEAKER: So I think in many ways, you have --

MR. BAYHA: (Inaudible).

PUBLIC SPEAKER: -- in many ways, you have our been our resource and information for the last 8 or 10 years and we appreciate it.

MR. BAYHA: Oh, thank you, Rich.

DR. KANABROCKI: Ryan, I'm not sure if this is the right place to ask the question but how is compliance going to be monitored?

MR. BAYHA: Well, it's an interesting question and I think it's a hard question to answer in general because for NIH, and I think for a lot of other USG institutions, much like any other policy, there is a lot of trust on the side of both parties. When you sign up for an award, you sign terms and conditions that say you will comply with XY and Z, you're going to comply with the animal welfare regs or you're going to comply with the human subjects, comply with the NIH guidelines. It's going to be much the same with DURC. You're going to say "yes, I agree to comply

with the provisions of the DURC policy." Obviously, if NIH becomes aware of, say, an NIH grantee that's not complying with the policy, we'll have to deal with that on a case-by-case basis depending on what the issue actually is. Obviously, if someone is just doing -- the usual issue we find with non-compliance is just a general misunderstanding or a lack of awareness of what the requirements are.

So our first tact is usually through an outreach mechanism where we'll re-educate you on the part of the policy that might be a little confusing or you might not be getting and then we'll work with the institution to ensure that they actually are in compliance in the future. So that's generally our approach, is to handle it as a partnership. Anyone else?

(No response.)

MR. BAYHA: All right. Well, if there are no further questions, I think we have a break until 2:45 so it's 25 minutes. I think it's until 2:45. Okay, so yeah, 2:45, please be back and

we'll do Panel 3.

(Whereupon, off the record at 2:16 pm., and back on the record at 2:32 p.m.)

MS. DOERR: Good afternoon. Is everyone ready to start? Welcome back, everyone. My name is Cheryl Doerr and I am the Compliance Assurance Program Manager at the Department of Homeland Security Science and Technology Directorate, and I have the great pleasure of moderating this panel this afternoon. Our panel is Raising Awareness and Education about Dual Use Research of Concern. So luckily, I don't have to talk much. My job is just to introduce three wonderful experts that we have right here.

First, we have Dr. Stephen Higgs with Kansas State University. Dr. Higgs is the Director of the Biosecurity Research Institute and Associate Vice President for Research at Kansas State University. He is responsible for oversight, coordination, and expansion of BRI's multidisciplinary research and education programs. He also serves as the Associate Vice President for

Research facilitating bio preparedness research campus wide.

Next, we have Dr. Richard Frothingham. Richard as an Associate Professor of Medicine at Duke University Medical Center. He directs the NIAD Regional Biocontainment Laboratory at Duke University which was built to support research, develop drugs, diagnostics, and vaccines for emerging infections and biological threats.

And finally, we have Patricia Olinger. Patricia Olinger is Assistant Vice President in the Office of Research Administration and the Executive Director of the Environmental Health and Safety Office at Emory University. EHSO has university-wise responsibility for all aspects of environmental, health, and safety support including biosafety and EHS compliance to support Emory Health Care. And without further ado, I'm going to turn it over to our experts.

DR. HIGGS: Well, thank you, Cheryl. It's a great privilege to be here. It's an honor to participate in this. What I'm going to do in

my allotted seven minutes, and I'm sure will somebody will waive at me when my time is up, is go through about 25 slides of how Kansas State University -- really, I am --

(Laughter.)

PUBLIC SPEAKER: I'm timing.

DR. HIGGS: and -- she's timing me -- of how Kansas State University has been addressing scrutiny of a dual use research compliance essentially, so that's my introductory slide that you see.

So this is what we've been doing up until now with the proviso that things are going to change somewhat because of new regulations being implemented on the 24th of September. So basically, all research on biological agents and toxins require a principle investigator to submit a registration document to our University Research Compliance Office. It's then reviewed by the Biosafety Committee. If there is animal research involved, it also goes to the IACUC. All PIs and all of their staff listed on those protocols that

are submitted must complete appropriate training. And regardless of whether there is a dual use research component or not, they have to do the training on dual use research; it's mandatory.

No research at all is approved without the satisfactory completion of that training and that training is typically good, as it were, for three years and then they get automatic notifications that it h as to be renewed, and then their research effectively could be halted unless they do that. And I go through all of this training as well even though I'm Director and most people try and keep me out of the laboratory these days, sad but true.

So this is where it starts. The principle investigators and their staff get a notification -- and like I say, I will be leaving these slides with you -- they basically are assigned different training modules dependent on the type of research that they are doing. For the dual use research, there is a box just down there and this is what it looks like. They all log in

with a unique identifier, basically user name and password. That allows automatic training of their progress to guarantee that they completed that training and then to send those reminders as it were.

So that's where they start and then they get a screen like this and -- trying to think, I went through this a few weeks ago over the course of a couple of hours or so -- you go through these slides, so there's our education, okay. This is the institution training for K State Research, dual use. And I've -- there are 41 slides. Don't worry, I'm not showing all of them. This is the fourth one and then I've selected key slides related to dual use research.

So it explains what the purpose of the training is, to have a positive impact on their activities and their awareness of this and there is a quiz at the end. It explains the personal responsibility of being an investigator and remember, all of their research staff are also undergoing this training as well. And, you know,

we take responsibility very seriously. We have to; obviously, the nature of the research that we do, we do a lot of select agent research in the BRI but we work with a whole variety of pathogens and toxins on campus, so people have to get this message. And we also have used NIH training programs as our basis for developing this particular program, so we're very much in line with what is already out there but a lot of this has been developed independently. As I said, we will change.

We give references. People can refer back. We give the hyperlink text to refer them in the hope that they are interested, and we know they take it seriously, but they are interested in pursuing and finding out more about the type of regulations and requirements that are involved.

We explain the scientific advances that could be used, so what does this concern; I mean a lot of people are working on, say, avian influenza that doesn't always spring to mind as a biological weapon, if you'd like, but obviously, that was an

area that was very controversial a few years ago in terms of dual use. So they get this explanation as to what dual use research is, how it might apply to them, the consequences, and what they can do about it to avoid accidently going down that track.

I have to say over years of scrutiny, we have not had a single research project that has fallen into the DURC category.

The IBC people, the IACUC people all look at these protocols very, very meticulously and one of the things I like about K State is that when they meet, they all actually invite the investigators to participate. That cuts down on a lot of emails. So they can ask the investigator pertinent questions about their research, about protocols, and really get to the answers very rapidly, face-to-face. That is easier than just doing the sort of email bounce back and forwards. But then the investigator does get an official request to address any concerns so that it is all well-documented.

I'm just going to go through some of these slides. It explains the U.S. regulations, puts it in the context of some of the international context as well, societal responsibilities. So like I say, it's putting to the investigators and their staff and most -- well, the principle investigators are working in the lab. I'm a principle investigator and I know their projects and I must admit, most of my research is now somewhat vicarious in that other expertise is used to do my type of research, but I still go through all of the training and sign on.

As you know, it was 29th of March 2012 when some of these discussions were really at the forefront and we've moved on from there over the last few years. Certainly, when those IBCs and IACUCs review protocol was -- there are some key indicators of what might sort of ring the alarm bells, if you like; one of my colleagues says for the seven deadly sins and then the 15 pathogens of what is under here. So any research that is submitted that involves any of these agents -- and

yeah, we've worked with Yersinia, Francisella, burkholderia, avian influenza, and anthraces -- if one of those agents is listed, that immediately sets the ball rolling as to the committee's questioning those investigators as to what type of research exactly are you doing and could it fit into, like I say, those seven deadly sins here in terms of, you know, enhanced pathogenecity, broader host range and things like that.

We constantly provide updated information but we also provide a resource for those investigators to be proactive on their own behalf and on their research teams to contact our University Research Compliance Office, the IBC, and IACUC. I know there was one question about providing feedback about -- the nice thing about our system is, like I say, investigators are invited to the meetings and are involved sometimes in quite vigorous discussions with the IBCs and IACUCs who look at the protocols very, very carefully.

You get to that point and then you get

the quiz at the end. At the moment, it's been this 10 self-grading questions which you register for and hopefully, well, you eventually get the certificate, one hopes, if you've done it successfully. Wrong answers lead you back to the slides and you have to go back through the slides to get the information you need, so it's kind of self-guiding.

So that's what we've been doing up until now and things are going to change. We know these regulations are coming into effect in about a month's time, two months' time, and we have everything in place to address the new requirements. This is just a brief outline of -- a summary of what we're going to do including the designation of an institutional contact for dual use research which is mandated and also establishing a new committee, which I am told I am going to be the chair of likely. This is a draft but I thought it's important to show you what we're going to do.

And we are going to be, obviously,

continuing with our education. We're actually moving from the current system that we've had which has been self-created back to a city-developed program which we know NIH is. So this is what the procedure at K State will be. How am I doing for time, okay? Good.

The PI will have the responsibility of informing the compliance office but as I say, the compliance, the IBCs and IACUCs are constantly looking for those pathogens of concern and the types of experiments.

The pre-award service will alert if a project has DURC potential but like I say, that's necessary but it's automatic, by the way, that our experts They will answer questions of, you know, is there an agent listed and does it have types of experiments that might be of concern. That institutional contact will then initiate the institutional research entity for a timely review. They will meet with the investigator. If there is a genuine concern there might be a DURC-type of project activity, then the investigator has to

develop the mitigation plan, and then that is reviewed.

There will be an appeal process which will be established by our Vice President for Research, and we will be able to call in subject matter experts on those types of pathogen if needed.

Training, all K State researchers are going to be required to take the City Collaborative Institute Training Initiative training on DURC as part of their routine applications, so just like they've been doing. It's going to be different courses. It's going to be courses which have been developed independently but which are already used by the NIH and many other things -- many other institutes, and that training will be required every three years.

So that is what we are doing and that is the end of my slides. Do I have time for questions or just an overture? Richard?

PUBLIC SPEAKER: We're going to ask questions at the end.

DR. HIGGS: Questions afterwards, all right.

PUBLIC SPEAKER: (Inaudible) for the questions together.

DR. FROTHINGHAM: Well, thank you all for hanging in there. Talking about training at three o'clock in the afternoon, we're going to give it a go. I do not have 25 slides, so Anyway, this is the disclaimer. These are my own opinions. Next slide. Oh, I have to do it myself, don't I?

(Laughter.)

DR. FROTHINGHAM: We'll sort this out. Okay. So I'm going to talk a little bit about what we've done in the past sort of as a background to this and I think as we think about what we've been doing, it has some insights to point us forward to the future. Clearly, this new set of guidelines, this new policy is new to us as well, but I think there is some foundation that we can learn from. So I'll talk about what we've done in the past and then whom do we teach and

what do we teach and we teach different things to different people I think you'll see.

So we've been doing this for quite a while. Historically, the NIH funded a regional Center of Excellence at Duke, the SERCEB, and it had a policy, ethics, and law core which focused on dual use from the beginning so in 2003, all of the SERCEB projects were reviewed. Coming out of that, the Duke IBC got a little encouraged to do the same thing so we started doing this in 2005. We put the screening questions on. We took the training together and we've been reviewing protocols for dual use ever since.

Interestingly, in the first few years, we came across quite a bit and my impression has been that as the years have gone by, we've found less and less and maybe we're just a little bit less aware of it these days than when -- than we were in the first few days when we were all geared up for it.

In any case, we reviewed protocols during the RDNA (ph) review. We had protocols

referred to us and we would take anything that came our way. We would talk about it. We didn't have a specific definition of ABC gets you into this review. So we reviewed a lot of things that wouldn't really fit under -- certainly would not fit under the U.S. Government policy.

We did publish on our experience in Science and this is just some case stories. This is the SERCEB experience, not the Duke IBC experience but there was some overlap between the two groups and the SERCEB referred things to us for review.

So what did we learn from this dual use review experience? And these are just the bullets of what was going on. As we look to these protocols, you can see dual use review potential in a lot of protocols. If you think about it hard, most biomedical research has some degree of dual use potential and without a definition, we talked about a lot of different protocols. The PIs, as we put these questions in and asked them about dual use and started questioning PIs, it was

evident that PIs, brilliant scientists did not really understand what we were talking about. And they said, oh, so you want more biosafety or you want us to wear PAPRs or you want -- well, okay, that's fine but that's not what we're talking about here.

Duke IBC members could not reach consensus on whether something had dual use potential or not so we went into this thinking well, let's make some categories and we'll say "minimal," "substantial." You know, we thought is -- we didn't have the dual use research of concern topic at that point, that concept. We thought well, is this real or not and as soon as we started talking about trying to classify research, it just went all over the place and our researchers would imagine scenarios and then our other researchers would say well, this is no different from anything else. And so we found we just couldn't classify realistically but we could agree on management strategies and so there is some hope there at least.

We found a few protocols. Here are some examples of some found early on and I'm just throwing them up there. A couple of things to notice about this, none of these would fall into the U.S. Government policy. None of them involve select agents. And also, none of them were identified by the PIs going forward. They were prospectively -- they were identified by -- in one case, the NIH study section said, "Whoa," which is kind of obvious, eck- familian cytokines (ph), that's interesting. And then our program officer contacted us and said, "Hey, this sounds interesting. Are you sure this is okay?"

We had the dual use questions on the registration form and we got a few nibbles there but more often, we would identify dual use potential during the review process and say, wait a minute, what about this possibility. And as I mentioned, this is a sort of expansion of what I said before. We were often able to say this is no problem and so, you know, propagating a virus in a cell line attenuates; yes, that's tropism changes

but it doesn't really bother us. But other times we had difficulty reaching consensus but we were able just to come up with management strategies and here are some of the management strategies familiar to you all, the kinds of things that we talked about: thinking about a contingency; if something comes up, the researcher is supposed to get back to us; things they will be looking for that might be potential issues.

We did not ever turn a protocol down but it was kind of sad one of the investigators, as soon as we started asking the questions said, "Oh, no, no, I won't do the research" and just backed away completely from the concept which was sad to us because it seemed like a good research project. They came up with a different plan but we weren't going to insist on that. It was just -- and I think this is a realistic risk here is that as a researcher, I don't want to touch this with a 10-foot pole; I don't want to deal with this; I want to -- and so do people back off of research projects that might be controversial.

Efficacy of our program, we've been doing this now for 12 years and we don't know whether we're doing any good or not. Here's our slide, you know, what has -- how it has happened since we've been doing this dual use review. Hopefully, this slide will continue in the same fashion. This is our hope -- there will not be any misuse of our research. But are we just -- we don't know. Clearly, there have been examples of consequence that have occurred in the world, so we're going to keep doing this.

So for the policy that's given to us, whom do we teach? And we've identified several groups that we need to train, okay. So first of all, under the policy, we're required to train all researchers who are working with any of the 15 agents. And fortunately, almost all of this policy is under select agents and every year we train our select agent. Everyone who is a select agent register has to be trained, and so as part of our select agent training each year, we have incorporated discussion of this policy.

So that seems fairly easy if it weren't for that little footnote that we've all talked about here about the botulinum toxin in limited quantities. And so, of course, we have policies for scrutinizing that and research labs that use botulinum toxin actually -- and this seems sad to me, too -- they've all given it up. None of the research labs are working with botulinum toxin anymore at Duke which surprised me when we went out looking and we realized that they'd all given it up. I hope that's not because they're afraid of the review.

We continue to be concerned and this is -- Ryan asked for feedback -- we continue to be concerned about this little niche of clinical research protocols using clinical product of Botox which seem to be covered by this policy, and that's not a big concern for us in the sense we have already got to do all this stuff but there are 100 other institutions that don't do anything with select agents that use Botox on their campus, actually hundreds, and if they do clinical

research -- so we kind of think we need clarity on that. I don't think that the intention was to regulate clinical research.

In any case, so what do you do with that? We'll get to that in a moment. How do we capture that? So we have trained all the members of the IRE, of course, and that's -- and we did use Ryan's slide set. Those 50 slides that you referred to, we went through them pretty quickly. And we have plans to train some of our gatekeepers out here. So here's the issue. How do you find this? For the select agent research, we have had these questions out there for many years. Are you working with a select agent? It's on all of the questionnaires but for the limited quantities of Botox, we haven't had it out there and we may need to go back and train some of these folks. We've done training sessions for these groups periodically and we're thinking we need to go back to those groups ad at least bring them up to date on this.

So what do we teach? And here's where

different groups need different amounts of information. First of all, our gatekeepers, the people who are going to be identifying this for us, the grant review people, the IRB potentially for a clinical trial of Botox, the IACUC where a researcher throws something in there that we didn't know they were working with. So we want to capture it as broadly as possible and there are the two basic questions: Does this research involve any select agents, which is already out there with, of course, an explanation of what are select agents and all of that. So we've been asking that for a long time. And I think this is about what our question is going to involve. Does it involve Botox or any other form of botulinum toxin in any quantity. The word "Botox," the clinical entity there to sort of capture people, say, oh, we are talking about the clinical product. I don't want to but we have to and then any other form in any quantity. And so -- but the gatekeepers don't really need to know where that's going. They don't need to understand the three

steps that we talked about this morning which are pretty complicated, especially to throw in there -- it's complicated. It's not simple policy. But they don't need to know any of that. They just need to know if you answer "yes," call our biosafety officer who is our ICDUR at this point.

Our researchers, okay, the people who are working with select agents, we talked about before we have incorporated this in select agent training, if we identify any research with botulinum toxin at the Duke Campus, we'll include these folks. And we obviously tell them here's this policy and then discuss the general concept of dual use. And I'm going to a few slides here about how do you convey dual use. And I think Stephen's talk was great, you're showing those slides. That's exactly the kind of content that we want to bring around this because as I've mentioned, our PIs don't really understand dual use in general. They are thinking in terms of biosafety, biosecurity, Biocontainment. And then discuss the different management approaches, which

is just because it's got dual use in it doesn't mean that it has to be shut down. And then, of course, briefly outline the U.S.

policy flowchart, not ion a lot of detail.

And here is what I just mentioned before, what is dual use. Of course, just a very simple definition, simpler than the definition that has been up on the slides. But an important point for our broad community is this is both materials and knowledge. The materials actually are well-contained and that's -- we've talked about that, biosafety, biosecurity, containment. All of that is going on. And so that's not the issue that we're adding here. We believe in all that stuff and as has been mentioned, that's a big part of our mitigation of risk for select agents. But is -- the knowledge is the challenge, the communication, what is it we're bringing out and then provide some examples along the way and some examples of management.

And it's three o'clock in the afternoon.

I thought I'd throw up just some fun slides, a couple of slides here that are more interesting of an example of dual use technology misused many times each month with fatal consequences. So I already told you we've not had any events at Duke that we're aware of and we've not had any events related to this particular technology but this technology does cause events -- that does cause -- is misused on a regular basis and --go ahead and throw that up there -- and that is the automobile. Most of you use that today and it's serious. I mean it's sort of a joke at some level but it's not. This is an example and I think it actually does convey, to some degree, both the issue of we need this technology, okay, we need automobiles, we're not going to give those up and yet they can cause tremendous harm, a tragic harm and do on a regular basis. So how -- thank you -- Cheryl's telling me to shut up. Okay, I'm going to move on.

So management, the automobile also gives you the management approaches that are available

to you. You can see the different ways we manage it and this is not only the infrastructure protecting us around there, but you'll see the redesign there, the open chassis design. If you're in an area where the risk is exceedingly high, you might end up with something like that. And so our researchers might redesign their experiments a little bit.

And then our institutional review, have to have the broader training, the 50 slides that Ryan talked about, our committee members need all of that. And here are some of the people on our team that are making this possible for us. And I'll turn it over now to our third speaker. (Inaudible).

MS. OLINGER: I only have seven slides, but those of you know me realize I can talk a lot between a slide. Well, first of all, I'd like to thank the organizers to invite me. One thing, coming at 3:00 in the afternoon after all these wonderful talks is that I keep in my mind changing my talk, and that's really a bad thing for me.

I'm Patty Olinger. I'm from Emory University. I'm -- people would be disappointed if I didn't talk about virus management. And I think one of the core things, I am the deputy co-convener for the development of -- actually, I am the, yeah, the deputy co-convener for the development ISO certification standards for virus management. The is something that the biosafety world and the biosecurity world has been working on, how long, 15 years, ten years, forever. We've gone from a workshop agreement to a workshop agreement, you know, from a development, and I can't say enough about those who have high-risk programs really need to think about an integrative quality system. Those of you who are healthcare providers understand that quality approach to things in a continual improvement program. We don't have perfect, and we all know that, and that step by step getting there is where we need to be. So Emory University, all investigators, I'm going to keep this really simple. My slides are very simple. All investigators are required to what we

call, would they submit a notice of intent.

Now, even before that, our, you know, and this gets into the Botox situation, even before that, our labs all are required to be registered with my department or, actually, with our research safety group. And what we do is it's kind of a trick. I don't mean to trick PIs, but it's kind of a trick. It's like, you need to have a sign for your lab. We need to have you register your lab. Are you going to be working with biological agents? If they click yes, it's like, okay, what agents are you going to be working with? And these are as they come into the university. And every year, they're required to update that.

So if they click yes, then we ask, are you going to be working with select agents? And then they have to look at that list. And if they have toxins, which one of them is botulism toxin, then I have captured that first risk to a risk assessment or first step to a risk assessment to see whether or not I need to go talk to them and

to find out actually what they're working with. So it's not really a trick, but it is a way to register those laboratories. So once they submit that and we start working with them, we talk to them about if you're working with biological agents, you need to submit what we call a notice of intent.

We're in the process of going to a completely new electronic system, and what -- and we include everything. We include recombinant DNA and regular infectious agents, including, you know, even chemicals of interest. So they submit that.

The notice of intent has a separate section titled "dual use screening," so it has all the questions that people have talked about today in that section. If we get a hit, then it's going to be reviewed even a little bit in more detail by the IBC, and then if it really were to be a dual use experiment, then we would go into more of an in depth review. No protocol for us is reviewed or is approved unless everybody has completed

training.

That's one of those things that, you know, if it's sort of, we have a few things that have to be completed. Have you done your self-inspection? Have you -- are you up to date on your inspections in your laboratory? And if not, they're not going to get approved. If everybody in that lab has not completed their compliance training, then they're not going to be approved. And so that is, it is an incentive for people to follow through on some of their compliance aspects. Now, the interesting thing is that Emory currently does not have select agents. Now, I do have patients that sometimes have select agents, but we're exempt, okay. But we're not a select agent site. We do have, we are one of the centers of excellence for flu research, and so we do have a collaboration with, for instance, University of Georgia, for our flu work. And they actually, and through a memorandum of understanding, they are legally responsible for the aspects of the select agent portion of that work.

We do have low pathogenic influenza strains used for research, and we actually have them come to our IBC and to talk about the types of research that they're doing, because as a lot of people have indicated today, back several years ago when the people first started talking about, you know, dual use research, and we could all come up with lots of different ideas and thoughts about, well, you know, that salmonella over here, if we did this and this and this, that could be -- well, what about this over here?

You know, and so on one hand, looking at the list of 15 agents and the seven questions that come after that helps us define what it is that the federal government or the NIH wants to look at, but on the other -- but when you look at that ethical aspect of it, we're still going to ask those questions and we're still going to review that research.

So training, training, to me, is one of those things that is a complicated thing. You know, many of you know my boss, Dr. David Wynes.

David is, you know, out there right now talking a lot about all of the impact that we have from a regulatory standpoint on our researchers and the administrative burden that our researchers have to go -- have to comply with on a day-to-day basis. It's not just biosafety. It's not just biosecurity. And, you know, the more that he has me in working with some of the other committees and some of the other aspects, I'm starting to better understand the impact that we have on the researchers.

The interesting thing about that is that the staff, the EHS staff, the biosafety staff, one of the groups that is interacting with the researchers more on a day-to-day basis than, let's say, grants and contracts or conflict of interest. And so we get, even though we may be one of the little boxes of the maybe 100 boxes that they have to go through and click to get their grants approved and reviewed, we get the brunt of a lot of their frustration. And so when we start asking them more and more to do training, what we end up

having to do is we're looking at that compliance aspects.

From a compliance standpoint, I feel confident that if we came in and were audited, and even if we had select agents, we would put in place the compliance boxes that needed to be checked. But what concerns me more is what really we need to be getting to and where that effective training needs to be. If I looked back at one of the lessons we learned from our experiences with Ebola in treating patients, I could've checked the box for PPE in the past. Yep, here's your gloves. This is what you need to do, and that Tyvek suit goes on here, but you would never -- I mean, for those of you who have gone through the hands-on training, where you put a physician in a Tyvek suit and spray them down with glow germ and then have him take it off, and the first time, it's like, oh, yeah, yeah, yeah, I can do this, not a problem, and then you have the head nurse come through and go, "Yep, you've got Ebola." It's a rude awakening.

And so my point on that is, a lot of the training that we do is really just click the box. Okay, I did it. But really where we need to be getting to is what is the effectiveness of the training and what is it that we need to be really focusing on. And it's not just the online training, which is quick, gets them back to the lab, back to the bench quicker. Sometimes it's face to face. Sometimes it's face to face due to the fact that we have language issues that have to be dealt with. And then our monthly newsletters, we send things out in monthly newsletters, but I don't know about you. I get tons of e-mails every single day, and it's getting worse and worse. And we've even gotten to the point where some of our higher risk PIs, Kelpin (phonetic) and her group will actually go and meet with the PIs one on one for, even if it's 30 minutes, to talk about, okay, here's what we need to do. This is what we need, why we need to do it, and how can we be there to help?

The other thing that I have to -- I

can't stress enough is the support staff. And the support staff is not just your biosafety and research safety staff; it's your IBC. For us, it's the research, health, and safety committees. It's also anybody, like, somebody had talked about, you know, the grants and contracts folks. There's a lot of ongoing education that needs to be done.

Our research safety staff and the biosafety staff that's supporting these groups are having to go to maybe the emeritus provider who knows more about this research than anybody else. Maybe they're the world renowned expert, and I'm going to go there saying, "You know what, you've got to do this." And teaching them just those negotiation skills and those communication skills is difficult. And I can't stress enough, and I stress to my staff, it is extremely important the need for collaboration with our research staff, to understand what their needs are. And then as you establish that relationship, you can then better explain to them what our needs are from a

compliance standpoint and from a safety standpoint, because, you know, quality research, we talk about that all the time, really, is it done safely? And it needs to -- and if it's done really well, everybody asks now a days, well, how do you know if somebody has, you know, culture of safety? And I've said, you know, I really have never met a CEO that says, "I don't care about safety." And, you know, we really need to shift to more of that.

I think one of my esteemed colleagues said that culture of accountability, responsibility, where, you know, we all know our roles and responsibilities, and we're held accountable for those, and part of that is working together in a collaborative team and finding what works and what doesn't. And with training and education, that is extremely important, and I don't believe we're there yet. We'll have our boxes checked by September 24th, I can guarantee you that, just like every single presentation that we heard here today, but I think we have a long

way to go from our educational standpoint, and I think we have a long way to go as to actually collaborating and working together. And meetings like this I think are important, because we all learn from one another. Thank you.

MR. DOERR: All right. We have a few minutes to answer questions, to ask questions, to start some discussion, to make sure that our web viewers are able to see this and hear this correctly. I would kindly request that you come up to the microphones to answer -- or ask your question. So please go ahead. Anyone have any questions for anyone on the panel here?

PUBLIC SPEAKER: Yes, Cheryl. I have a question for Dr. Higgs. I was interested in your appeals process that you mentioned, that the researcher could go back to the IRE after a dual use research, DURC finding for the research project was made. My -- my question is, how is that going to impact your reporting to the funding agency? Are you going to report when you -- when the IRE makes the finding of DURC? Are you going

to wait until the appeals process has gone through its machinations?

DR. HIGGS: My answer is that I honestly don't know at this point as to how that will be -- be managed. We're hoping that this review process will be very rapid. I mean, as a researcher, you know, that is what we expect. It might not be what we always deserve, but it's certainly what we expect. The IBC and the IACUC meet regularly, I think every couple of weeks or something, every month, as needed. So the review process should be very rapid.

Certainly, when research applications go through our pre-awards office, there are check boxes regarding, you know, do you have IBC? Do you have IACUC approvals? A lot of us, a lot of people check, you know, pending, and then jump on it straight -- straightaway after that as the decision is made, especially if it's funded, obviously. But that approval process should be implemented very quickly, depending on the review of the risk mitigation plan, and then as

necessary, subject matter experts, who we would identify early on would be called in to do that. At what point, you know, I mean, if it was obviously, dual research, dual use research of concern, we would be communicating with the funding body very, very early on.

MR. EPSTEIM: Hi, Jerry, Department of Homeland Security. As one of the Feds who was involved in helping put this together, I really -- well, I appreciate all of the speakers today, but especially those of you who have brought your experience in having done this for a couple of years, because that's really going to give us a head start in building the case law and trying how this works in the real world.

Along those lines, I really wanted to emphasize something that Dr. Frothingham mentioned from the Duke experience, which really struck me, which is that you often couldn't agree on whether something was DURC, and I can imagine lots of arguments and lots of heated discussions by people in the room here on that third question. We know

it's an agent. We know it's an experiment. Is it DURC or not? And what you told me is that really may not matter that much, because you ought to talk about what you can do about it, which you may not have any arguments over. Once you come up with mitigation measures, you either have a head start on what you're going to be telling the government if you call DURC or you can do it anyway even if it's not DURC, and that may be the easy part. And once you've done that discussion, it maybe doesn't matter so much if it's DURC or not.

Yes, we need to know and it's part of the process, but I would urge people nod to get stuck on that question and go on to the next one. And if you can all agree on, well, we don't know if it's DURC or not, but here's things we ought to do, it maybe doesn't matter so much. Yes, you have to pick one, but the important stuff is that you're doing something useful and you will be mitigating risk.

And, finally, I really appreciate your

chart on showing evidence of success with your zeros and your -- one change to your vertical axis might make that chart a lot different. And if you label your vertical axis not incidents per year, but ability to defend yourself to the public that you thought things through, it's zero before that and it's 100 percent after that. Doesn't mean you thought it through right. Doesn't mean you've got all the answers, but you actually have something you can point to as, hey, we're not blundering through it. We are not one of Susan's cowboys in the Wild West. We're thinking this stuff through, and that's a really important output.

DR. FROTHINGHAM: I really appreciate the positive feedback. We've had fun with this. And, you know, these management strategies, I'm not at this level of duteous research of concern with one of these 15 agents. We haven't seen any of that, but it is possible to improve the environment of research at these much lower levels of risk, and some of the strategies that have worked is obviously dual use training, just in

general, not related to these 15 agents, just general duties for training, and then asking investigators to think with us about what are some of the outcomes that could pose real risk and how would you find them? How would you identify them? And what are you going to do if you encounter them? So that's basically what we've done so far.

MS. DOERR: In the interest of time, we're going to take one more question, but I wanted to let you know, at the next session, it's an open forum. So if you have more questions about training, more questions about education, more questions about outreach, I highly encourage you to ask it during that session as well.

MR. DOYLE: Thanks, Cheryl. Hey. Brendon Doyle, EPA. Do any of you do research using one of those select agents or toxins listed in the policy that's funded by a non USG source?

DR. FROTHINGHAM: We have some collaborations with Novartis Pharmaceuticals, and so that could potentially involve the high-path avian influenza, yes.

MR. DOYLE: And so are you following what we call the reach-through provision of the DURC policy to report that to NIH?

DR. FROTHINGHAM: Well, none of it has involved -- it's a collaboration that may involve high-path. We don't have high-path with that collaboration to date, but, yes, certainly, I mean, the principle is something just to mention, Duke receives NIH research funds. Everything we do at Duke is covered by the NIH guidelines on synthetic and recombinant DNA. Similarly, we receive these funds. Everything we do is covered by this policy. We affirm that principle.

So, yeah, if the time comes, that's where Ryan comes in. I'm going to call Ryan and say, "What do I do next?" And he's going to -- he's going to either tell me or he's going to send me to the right person. And, again, he answers his phone, so he's the one you go to.

MR. DOYLE: We've been calling Ryan too.

MS. DOERR: We've been calling Ryan too. Thank you, everyone. I really appreciate it, and

we're going to move on to the next session. Thank you for the participants.

MR. BAYHA: Just before we start this next session, I think the people out at the registration table wanted me to ask, if anybody needed a taxi, to go sign up now, because the only thing harder than getting into this place is getting out of this place. So if you need it, I think it takes about an hour for a taxi to get here. So we end at 4:30, so this should be right around the time if you need it, you can go out and sign up for one at the registration table.

MS. COLLER-MONAREZ: Okay. I'm going to invite the federal representatives that we had spoken with earlier to come down and have a seat at the front table. Ryan, that's you too. In case the Feds have forgotten who they are, if you moderated a session or otherwise are a key stakeholder in this. Okay. We are missing Dennis and DHS.

Okay. So I will be really honest, we design this last session as sort of our catch-all,

knowing that we were going to have a significant discussion across all aspects of this policy, and so we wanted to make sure that if there was anything that had been highlighted during the course of the discussion with the shorter question-and-answer periods after each session, that we would have an opportunity to discuss it. And also, if there were any more general topics that you wanted to bring up, to make sure that we had additional things to take back, that we offered you this forum. So I have been taking notes over the course of the day, and I've highlighted about six different questions, which I'm happy to go into, you know, to pose to make sure that I've captured some of the sentiments accurately. But I think what might be productive is if there are any wrap-up questions or any final thoughts that anyone from this audience wants to -- - now that you have, these are the federal representatives, who when you think about who are those Feds who are putting the policy in place? This is them. And so it's an opportunity to reach

out to them directly and ask any questions that you want to see addressed.

So with the microphones, and we'll go through. So start here.

MS. ORR: Hi. I'm Kimberly Orr in the Department of Commerce. This is more like a public service announcement. I've heard people talking about publication restrictions, fundamental research and things, so I just want to remind you guys that there's two Federal Register notices out there that you need to look at. June 3rd was for the combined EAR and the ITAR definition reconciliation, and June 17th is Category 14, which involves biological research. You can see both of those Federal Register notices on the Commerce website or at the Federal Register, and I suggest that you read them, and remember that you've still got time to comment, because all this is going to interplay with everything else, so just a PSA.

MS. COLLER-MONAREZ: So before you wander off, Kimberly, I did want to pull on that

thread. This is one of the areas that I captured is it's still been subject to a great deal of discussion is the post-manuscript development, but pre-publication, and how you might consider ensuring that there are -- the DURC sensitivities are appropriately communicated. And I know that we've had some conversations internal to the government. Did you want to talk a little bit more about the implications, or did any of the panelists want to offer their thoughts regarding, you know, how one might systematically think about that to remain in alignment with the policy?

MS. ORR: Really, I don't. I think I would just suggest people look at the -- at the charts, and maybe see if they have some comments, and because it's kind of in flux right now, and that other discussion was high level by lawyers, so I'm not touching it. Sorry.

MS. COLLER-MONAREZ: Understood.

MS. CARUSO: Good afternoon, everyone. Rebecca Caruso from Harvard. I thought this was really a helpful discussion today, and I took a

lot of notes, I think, on what the -- some of the unanswered questions were, but one that I brought from my colleagues at Harvard I wanted to share was basically something we're challenged with, with our IBC at Harvard is when the work isn't on one of the agent lists, it's not one of the 15 prescribed agents, we have actually been reviewing a lot of these projects at Harvard for DURC. We had a sub committee that reviewed the DURC policy, and we currently use our IBC for the review of these DURC projects.

So my general question is to the panel, would originally harmless bacteria that are then engineered to produce federally regulated substances be considered DURC? For example, a harmless E. coli in three steps could be produced and chemically altered to make a drug. And I would also ask them to consider if quantities should be considered in part of that discussion.

MS. COLLER-MONAREZ: That's a great question. It's also one of those that I've captured as we're going to have to address it

eventually. Does the panel?

MR. BAYHA: I guess I'll bite the bullet. I think the general answer would be, it's not subject to the policy unless it's one of the 15 on the list. However, if you do have concerns about projects that involve agents that are not on the list, we would encourage you as an institution to contact your funding officer, your program officer, who's funding that project, to discuss it with them in case they had any recommendations or things that they wanted to get involved with, with that project. It wouldn't be subject to the policy, but the policy does specifically state that it realizes that the universe of DURC is not just those 15.

Obviously, there could be many other projects that could potentially be DURC that don't involve those 15. Right now, it is scoped to that limited 15, just so that we can kind of see what the implementation is like, and then discussions can be had in the future about whether any augmentation needs to be made, but right now, it

is limited to those 15. But, again, the take-home message is really is, if you have concerns about any project, you should always contact your program officer or your funding agency to open up a dialogue.

MR. EPSTEIN: Let me say the same thing, but a little bit differently. I think it would be great for institutions to assume whatever they would like to do in terms of reviewing anything. I think what we heard from the earlier panel was there's great value to doing things at the institutional level, asking these kinds of questions, even if it doesn't formally rise to the level of reporting to the government. But I would also second the suggestion to contact your funding official, not only because there could be some useful advice and interaction, but it's important to us to know the other things outside the formal policy that are raising questions, because we will be looking at the policy, and it is important to know, we will be deluged if we extended it to such and such, or, you know, we put the same process in

place for things that were greater than the list you had, and we actually found out we could do it. I mean, both of those answers are extremely important as we evaluate the policy going down the road.

So we realize there's got to be some happy balance between predictability and stability and implementing something, and having things locked in that really shouldn't be that way. So we will be looking at this thing, the change, hope, you know, not before we get the first one in place, but at some point down the road, we'll be trying to make sure we've got it right, and that kind of feedback will be very important as we evaluate that.

UNIDENTIFIED PANELIST: This goes along with the whole aspect of both the 2012 and the 2014 policy, and that's a culture of responsibility, and I would -- I would suggest to you that I think it's excellent that if it's not on the list, you still should be looking at these things, because they have great potential for

doing harm.

DR. EDWIN: One of the examples that comes to my mind is monitoring synthetic genes. That's something we started to track, especially the ones that have -- that are from the select agents or these 15 agents. I think it's just prudent to be able to, whenever you see something that has the potential, you better have a plan in mind.

MR. KOZLOVAC: Yeah, I think it's basically just a good parted of being, creating a culture of responsibility to look at those things. I think it's also good biosafety and responsible research, because we're not going to capture everything on -- on a single list. And let's face it, lists will change more than likely over time. So I think, you know, to be part of that robust discussion as we go forward is -- is a responsible step for the microbiology community, science community to take. Thank you.

PUBLIC SPEAKER: I just had a few questions, some issues that I was confused about,

and I was hoping there could be a little clarification. The first one is, citing or referencing previously published material that could now be considered dual use research of concern, in my mind, I'm thinking of information, I'd say, passage through an animal can increase virulence, or I was actually talking with someone else, and they mentioned that publishing a new piece of information on a previous project could complete a picture, which would allow someone to -- - to -- I'm sorry, to complete the picture and allow them to then apply that research in a negative way. And I was wondering if there was any guidance on how to treat things that have already been brought to the public.

MS. COLLER-MONAREZ: That's a great question. I mean, it's sort of like the DURC by compilation issue, and I don't know if there's any thoughts on that. It's -- we have not -- we had not, as far as I know, in the interagency, talked about is there any mechanism to evaluate if -- if three out of the four pieces of the puzzle have

already been published, and this fourth piece is the key that then allows someone to use it in an immediately harmful fashion, what would one do about it?

MR. EPSTEIN: I think in your case, the fourth piece that's actually new would be going through the policy, qualified, evaluated in the context of the other three. If your question is, are there things out there in a published literature we are going to pretend aren't there because we hadn't had this in place? The answer is no. I mean, whatever is done is done, and we would not be -- it's not like it's Nazi research, which is unethical to use. So you wouldn't be retroactively trying to apply this on previously published work, but new research which otherwise is in the realm of the policy, part of the risk and benefit assessment is how -- what additional information does this add based on the sum total of the previously unaware.

PUBLIC SPEAKER: Okay. And I was especially interested in the context of, well, I'm

building on previous research. I'm published. I'm still doing these procedures. I need to have a virulent strain to do -- to study a particular disease. So, you know, it's new research in that it's part of the body work I'm doing, but I'm still referencing something that already exists. Then am I going to redact my materials and methods? Am I going to reference something older? Am I going to gloss over it? I mean, I'm just kind of curious about how you -- how you see this, if you see this as an issue, and if not.

MR. BAYHA: Well, I think, just in general, I think a common theme throughout the day has been kind of this palpable fear about redaction, about prescripted communication, about classification. I think it's always been said from the beginning that the default position is always free and full open publication. That's always going to be the government's default position, and that in very limited, rare circumstances, it might be necessary to do those type of redactions or classifications or things

like that, but that shouldn't even be the normal when it comes to DURC. Because I think there is this task to try not to stigmatize this research to the point where if you, like several people have said, where people just don't want to do it anymore, because they feel, well, if it's potentially DURC, I'm not going to be able to publish it. Why even do it? I think it has to be looked at through, I think from the very beginning, we said that only a small subset of projects would actually be determined to be DURC, and I think through the experience of some of the people at the institutions, I think they have shown that a very small amount would actually get down to meeting the definition. But of that small subset, I think it would be a very rare circumstance where redaction or any other type of those efforts would actually need to be done. The position is always publication.

MR. EPSTEIN: I'm sorry to keep getting to you. One more second. But on this elephant in the room of redaction, the whole way in which this

policy gets at things that might not appear is through the researchers and the institutions deciding on the basis of conversations and evaluations, you know, I don't want to publish that. In many cases, the government has no legal authority to come in and tell you not to. That's not true for contract funded research, where I think there is more legal authority on the part of the government, but research funded by a grant, I don't believe there's a legal mechanism to force a researcher not to say something. But the hope is, in that rather instance where the researcher and the institution and the funder jointly decide I'm not holding it as a requirement, but as a hope, if everybody decides the world is more dangerous in saying something than not saying something, it would be the authors that made that decision, so it's not like the hand of the government is going to be coming, clamping down.

MR. BAYHA: Yeah, that's a good point. And I think that's where really highlighting the benefits of the research really comes into play.

Because like Joe said earlier, if you can't very easily kind of show where the benefits outweigh the risks, that's a different conversation. But if you can really articulate the benefits of that research, it might obviate the issue.

PUBLIC SPEAKER: Thank you, appreciate that. And then my second question -- and I apologize for monopolizing. I'll speed it up. If you're collaborating with a lab that is outside the U.S. and not dependent on your same funding source, would -- would a PI's name on a paper that is -- that is seen as dual use, would that cause trouble? Would they be seen as non-compliant in that scenario? And that's my last question.

MS. COLLER-MONAREZ: So just to clarify, so maybe you're not off the hook yet, so we have transnational collaborations on a routine basis. I think that's fantastic and should be fostered. So was the question, if the U.S. lab is under compliance for this policy, but work is being done, say, in France, for example, but they're not necessarily, you don't know or they haven't

implemented an IRE in that type of policy, are there any vulnerabilities with that relationship or that work or that lab?

PUBLIC SPEAKER: Yeah. Would I be held responsible if I'm on a paper that is considered dual use research of concern, but it's been -- the first author and the hosting institution is also, and they're not under that regulation.

MR. BAYHA: I don't really think it's an issue with the paper. It's more the funding, where if the reach-through provision for international research was that a federal agency was providing the funding to that international entity to do that research and it did involve one of the 15, it would be subject to the policy since it involved federal funds. Just that project would be covered, though. It wouldn't be the reach-through where the entire international organization would be covered, so I don't really think the publication issue about whether you just happened to have your name on a paper with someone that's conducting DURC. It's really more, I

think, of a case of where the funding is coming from for the project. So if no USG funding is being given to that foreign institution and they publish an article and you just happen to have your name on it as well, as long as you in the U.S. were adhering to the policy, I don't really see any issue with the publication being non-compliant with the policy. It's really immaterial to it.

MS. BOHN: Hi. Sherry Bon, University of Maryland. First of all, I thought this was a great symposium, chance to talk, chance to hear everybody's perspective. In listening to this today, I've heard a couple things, and they're not exactly questions, but things to throw out there. Maybe people want to talk after me about this. From more of the regulatory side, I'm hearing things like form your committee and have your icter (phonetic) and all that kind of great stuff. And then as I listen to my academic, more academic colleagues' presentations, that they're using the IBC. They have the IBC. The icter is the BSO,

who already has three other jobs as well. We're -- I don't know if it's just me, but I'm having a hard time getting people on the IBC. So if I have to stand up a completely separate committee, separate people, I have a limited -- well, it's a huge university.

I have a limited number of resources of people that are willing and able and competent to give their time to these kind of issues when it's, you know, unfunded. Sometimes we get lunch. So that's actually kind of tough to manage. And as we've worked through this year how we're going to implement and how we're going to change how we're implementing and how we're going to grow, that's actually one of my biggest gut research wrenching things is, who am I going to get to do this? It's really hard. And then on that theme as well that I struggle with on the IBC route, and I can see it struggling here, is we've talked about doing things at implementation or pre- implementation and stuff. And one of the things with dual use is that things can come up during the course of an

experiment, the unprepared for, the un-thought of or whatever, and we approve things for three or four years. And, yes, they're supposed to come tell us, but I'm struggling with post-approval monitoring type activity and really getting in there and finding good ways to do that. And it concerns me with IBC and it concerns me with DURC, and I just think that's something that we can, we might talk about, or that if people have good ways that are doing it, this might be a way to share in double resources or whatever. Because it's just something that I'm really struggling with.

MR. BAYHA: Yeah, so I think from the lens of the IBC, Katherine Harris and I, we do site visits to IBCs nationally to assess their program. So far, we've done about 112 sites. It is a problem with post-approval monitoring. We do see the three/five- year model, where, you know, the researchers approve for three or five years, and the NIH guidelines do have this notion that you periodically have to assess the research that you've approved. We find it's better if the

actual annual approval is initiated by the IBC, or maybe in this case the IRE, where it actually comes from them and you have to actually proactively go out to the investigator and say, has anything changed in your protocol, as opposed to putting it on the PI for them to come to you and say, "By the way, something has changed."

The rationale for that being is that if you use, you know, lab research as an example, if someone has an epiphany in the middle of the night about a great new thing to add to their experiment, their first thought is usually not let me do this great thing after I contact my IBC and my IRE and my IACUC and my, you know, my IRB if necessary. So generally having it driven from the IBC side to have an interval where you're actually going out and polling the investigators and saying, is anything changing, rather than relying on them coming to you, is a system we usually recommend. In terms of the resources for the IBC and the IRE, I definitely sympathize with that. I mean, from our site visits, we see that

getting quality people to serve on these committees can be difficult. I think a lot of institutions are going to utilize their IBC as their IRE. I'm not really quite sure how to handle or answer the resource issue or the drain that will actually put on them, but I would assume at some point, you would also need to augment that IRE with other expertise aside from who's on the IBC.

So, really, it would be more interesting probably to hear from people in the same situation how you're dealing with a circumstance like that, where your IBC is your IRE, and there might be a certain degree of, you know, overload on the IBC from taking on this new task, and how your institutions are actually handling that, and how you're actually acknowledging that service so that they don't get burnt out on it. So I think I would be interested to hear from the institutions and the audience how they're doing.

MS. COLLER-MONAREZ: Yeah, I would too. Thank you.

DR. EDWIN: One suggestion that I have is to review the progress reports, you know, just as you have access to the main research proposal. You know, if we delicately look at the progress reports, at least that's one part of the equation that will help if there is a change in the procedure.

MR. BAYHA: And I guess one other aspect is, you could also kind of multi task your chores here. You can kind of perform a lot of these reviews with talking to the PI about whether anything has changed during lab inspections. It doesn't necessarily have to be a secondary process where, okay, it's January 1st, time to send out the notice. It could just be every time you're in the lab, you just check in and say, "Hey, just, you know, checking in. This is what we have down for you. Is this still what you're doing, or any plans for changing in the future?" And kind of having that personal level of service is a good way to get compliant as well. I know it's tough if you have a lot of labs and not a lot of people.

You can do it, though, obviously, but if you can't, you know, there are definitely other mechanisms.

MR. KOZLOVAC: One of the things that I found useful when I was in academia, running multiple IBCs, what we would do is each registered project, we would actually send on an annual basis, or if it was a higher risk, maybe even somewhat more frequently, but minimum on an annual basis, it would just be a one- pager saying, "This is what you're registered for. Here are the folks that are in here. Here are your spaces. Has anything changed? Has anything changed risk?"

And if you do that, it's really easy to get a lot of good feedback from that. But also, when you are out in the lab, use those teaching moments and really reinforce, you know, culture of responsibility. If you're doing something to change risk, be it from a biosafety standpoint or from a DURC standpoint, that you're reporting that as soon as possible.

DR. EDWIN: One other thing that we have

done is to attack this as a piecemeal, and ask the research proposals are being submitted, and sort of making it a quarterly event or a semi-annual event or an annual event. Then it becomes really monumental. As soon as the research proposals are submitted, we attack them on a piecemeal basis.

MR. BAYHA: One other thought I actually had was involving, you know, if you have a specific college or part of the university where you know a lot of this research is taking place, it's going to be very important to engage the leadership of that college, the Deans and the people that are in charge of those researchers, because we've also found that a lot of times if someone from, you know, EH&S, or maybe a biosafety officer or someone else send an e-mail, it might get disregarded. Investigators many times won't disregard a direct e-mail from the Dean or, you know, someone that's in their structure in the facility. So that could be a way too to leverage that relationship with the facility to ensure that the PIs are compliant.

PUBLIC SPEAKER: My name is Patrice Binder (phonetic. I come from France, and I am advisor for security of defense of the president of International Reserve Center for Medicine in France. First of all, I would like to thank the organizer to have invited French at this interesting and very fruitful meeting on the direct reserve concern. Of course, we have no organization like yours, and but we have some information. So I would like to speak about the question of regulation for reserve center.

I think we have exactly the same view and the same approach of views, not in the organization, but in our concept. And if we -- and if you have a question about corporation on a special drug that is concerned, it's always -- it could be possible to discuss about the question, and I am sure that it was able to tie and to find a convergence, very happy convergence, not only about the founding, but also about publication and the follow-up of the research. In France, we have not very (inaudible) on this question, but we have

discussion on that. And, in fact, we have one major experience with special institute on this -- on this question, because three years ago, we were contacted by the (inaudible) community to organize a follow-up of a drug use concern of large (inaudible), including research on influenza, including research on -- I don't remember the name. And in the research, we -- 17 labs from different country in France. And each year, we have a review for (inaudible), not only for animal research or human research, but also on dual use. And we have had reflections years ago on a questionnaire, and the questionnaire is particularly your questionnaire. It's not seven questions; it's nine questions, but it's particular, exactly the same questions.

At the beginning of the research, the researcher was not very familiar with this questionnaire, and we have had a lot of question what is your question? Why do you have this question? We don't make research on values; we make research on epidemiological infectious

disease, and we have explained the reason of this questionnaire, and the stuff of labs, organized reflection on this questionnaire. And after three years, we have had good comprehensive response at this questionnaire, and the organization of this process was a good example of education, and response of research in this question, and I appreciate your reflection on the process of the data, the researcher to explain what is the drug research, what are the program's responsibility in this question, and I think we can use your reflection and your advance on this question to -- for our experience. Thank you.

MS. COLLER-MONAREZ: Thank you. Yeah, so, yeah, again, I want to compliment everything, you know, everything that we talked about and we saw when we came over to Paris last year. It's so clear that we are of like mind in talking about the risks posed by dual use research of concern, and it's not -- I mean, it's a two-way learning experience. And so as you are working with your labs and those, the PIs there, this is the type of

international dialogue that we need to maintain, and Ryan highlighted some of the areas that are being worked on in the international community. But it is important that we have a global dialogue.

I don't know, Ryan, if you wanted to say anything more about the international coordination on this.

MR. BAYHA: Just like Susan was saying, that we are of a like mind, and that there's cooperation involved, and the international engagement continues, because it is a global issue; it's not just an issue that stops at our border. So, yeah, I would concur with everything Susan said.

MS. COLLER-MONAREZ: We actually have Meg Flanagan from State Department. I don't know, Meg, if you wanted to say a few words about the international coordination.

MS. FLANAGAN: My name is Meg Flanagan. I work in the office within the State Department that leads U.S.'s participation in the biological

weapons convention, and that's a forum in which dual use issues have been talked about for some time, but definitely with an increasing frequency over the past handful of years, I'd say. And state's parties to that treaty are increasingly interested in implementing some sort of national measures to address dual use research issues. And based on what we've seen so far, different countries, of course, are using different measures to achieve that aim, so there's really sort of a wide variety.

There's the way that we do it, which you've heard about a lot today, and there's also the example of Germany, for example, that is using some of its current regulations with regard to how they regulate genetically modified organisms, GMOs, to try to address some dual use research issues. So it seems as though we necessarily all use the mechanisms that are readily available to us, and I think that's pretty reasonable. But at least for now, the land escape of what different countries are doing is pretty varied. And I'd say

it's an exciting time, because it's still early in the process and we're still on a position where we can influence one another and share our good ideas so long as we communicate as we have today with our French guests.

MS. COLLER-MONAREZ: Thanks, Meg. Okay.

MR. EVANS: Nicholas Evans, University of Pennsylvania. I have two clarifying questions. Susan, should I pitch them at the same time or --

MS. COLLER-MONAREZ: Yeah.

MR. EVANS: -- one after the other? So the first relates, and I think both of these relate to the agency's relationships with the IREs and the institution's. The first relates to standards of evidence. Now, it seems clear that not every dual use research of concern assessment is going to look like the current deliberative process that's going on, and people aren't going to go out and hire Griffin Scientific every time they need to find out if something's DURC or not, but what types of evidence are we looking for regarding the benefits and the risks posed by

these individual cases of concern as they come up in institutions, and what is desirable as this policy is implemented?

The second question has to do with compliance. It's been a bit of a public relations disaster for biosafety in the last year. As this process moves forward, what are we looking for in terms of compliance with this new policy? What does non-compliance look like, and what are the consequences for non-compliance in the policy?

MS. COLLER-MONAREZ: Great questions. Does anybody on the panel want to address any of those?

MR. BAYHA: I think I'll take the non-compliance question. So for not -- it's a good question. Like I said to Joe, it's a relationship of trust that when you sign on to accept USG funds, you sign on to agree to certain terms and conditions of that funding, so you'll agree, for NIH example, you will agree to comply with the terms of the DURC policy. If non-compliance comes up, like I said, it's hard to give an answer right

now about how we'll deal with non-compliance, because the world of non- compliance can be very varied. It can be from someone just forgot to submit notification within 30 days to someone doesn't have an IRE, so it's really going to be dependent on the type of non-compliance. But like I said earlier, our effort is or our default expectation or our default position is usually that the non-compliance would result from either a misunderstanding of their obligations or a lack of clarity on how to actually do what's requested of them. So we'll work with them from an outreach perspective to rectify that non-compliance so that it's not an issue in the future. Like all -- like the terms and conditions of all grants, there are penalties where if there is willful non-compliance, the penalties can lead to the loss of funds, the limitation of funds, or the disbarment or you can't even apply for funding, so that is an option we would have as well if there was willful disregard of the policy. But in terms of what specific compliance actions would be taken, it

would really have to be tailored specifically to what the non-compliance is.

DR. EDWIN: I want to remind them this, that some of the experiments will also come under the restricted experiments of the selection regulations, so that part of it is not going to be negotiable.

MS. COLLER-MONAREZ: So while we have a lull in microphones, one of the things that I think we've all touched on, Jerry just highlighted, and I know I've said before is, you know, this is the first opportunity to implement this policy. It's a new policy, and we are anticipating that it will have some growing pains. And what we need to be open to as the government, and I think we are, and you need to be thinking about from the institutional perspective is helping us with data. So we've talked about two essential data points, three essential data points, and the first is the cost associated with implementing the policy. It's unclear, any policy when implemented seems like it's going to be

resource intensive.

I was just talking to Rebecca Moore about this. Is this policy going to be so different than the IBCs and everything else that's in place right now, that it is really going to demand additional resources above and beyond what's already available for safety, security, and other aspects of this? And if that is the case, it's really important to be able to with empirical say this is what it costs us to implement it.

As we continue to evolve our thinking in the DURC policies and the gain of function policies, thinking about better ways to streamline implementation if there is, indeed, a critical cost associated with it, can be something that is incorporated. I mean, obviously, we are trying our best to make sure that these policies are not overly burdensome for the purpose that they are going to serve, but the empirical evidence associated with the cost I think is critical. We've also talked about PIs being compelled to not pursue research or having scientists or students

going into a field because of the DURC policy.

Again, it's one of those issues where it's one thing to have anecdotal evidence. You know, there's a PI down the hall from me, and his student was thinking about going to work in an influenza lab, but then he saw that there was a DURC policy and decided that that wasn't going to take place. It's one thing to sort of highlight that as an anecdote. It's an entirely different thing if there's a quantifiable decrease in the number of students that are actually being recruited to these labs.

It's a very, it's a key data point. You know, if that bears out, again, it's on -- nobody who's sitting here on this panel or who's in my office at the White House wants to be an impediment to science. Again, it's just mesh work that we're trying to reduce the potential risk posed by this. And so being able to go from, you know, the guy down the hall who didn't get a student, to actually understanding that we've seen a decrease of now 150 students influenza labs in

the past two years, which coincided with the implementation of this DURC policy, that's a big deal.

And then the last data point that I think is going to be absolutely critical is, as Jerry highlighted, the case law. All right. So we are going in this, and we don't have -- you know, I love the slide where there was no change, right? I mean, you put a policy in place and nothing happened. You know, Ryan highlighted this as well is, we don't know, you know, if there's non-compliance, because we haven't had an issue of non-compliance because the policy hasn't been put in place. We also don't know how each institution -- we talked about the various points of subjectivity across the policy. We don't know how institutions are going to deal with that, with the subjective third pillar of, you know, is it DURC or not? We don't know how many DURC research cases each institution will identify once they put this policy in place. All of that, and we won't know what the IRE's deliberation process was.

I mean, these are all key pieces of, you know, information that as we continue to evolve this policy, we need to have, and we need to develop some sort of systematic fashion to be able to get that in, so that a year from now or two years from now when this policy is being updated or we're integrating the gain of function policy into this, and somehow, you know, creating, you know, a more comprehensive policy, that if there is something that we need to change to make it better, better for the researchers, better for the government, all those sorts of things, we need to have that evidence base and that case law of highway IRE evaluated DURC, how many were coming from small institutions, public land grant universities, any of those sorts of things, so that we actually have something to reflect on, more than just the sort of more anecdotal discussions that are very informative, but they don't -- they're not -- they're less persuasive in terms of modifying a policy than if we have something more systematic.

Did anybody else want to make any comments on that?

MR. BAYHA: Yeah. I would just echo those sentiments, and I would say it's very important just to hear the actual feedback from when you're implementing this policy. We want to hear what the stumbling blocks are. We want to hear what the challenges are so that we can potentially address these. Like Rich brought up with a great point with the Botox thing, you know, it might not be a problem for his institution because they already have an IRE stood up, but if this is the only thing that brings you under the policy, that might be a little burdensome. So we do want to hear the implementation challenges, so that, like Susan said, when the policy or if the policy needs to be revised, we're actually doing it based on real experience and not just kind of doing it because we think it needs to be done. So your feedback on this is extremely valuable.

MS. COLLER-MONAREZ: Okay. So we are at the end of our question/answer session. So if

there -- are there any other final questions for our federal panel members?

We've exhausted you, your imaginations. So thank you, all of you. So I am slated to give a wrap- up speech. You know, we -- I think this has been an incredible conversation. I don't want to spend a great deal more time rehashing the many great comments that we heard over the course of the day or the presentations that we've heard from our panelists. So I don't -- I don't have anything that -- I want to make sure that you walk away that you already don't have in terms of the dialogue, other than just that final point, which is this is a partnership. The government and life sciences researchers, we're all in this together and we have the same goal, and so we need to have meetings like this going forward, and we should try to do this on a periodic basis so that we do have an opportunity to update these policies as they are appropriate in terms of both the evolution and the government structures and the evolution of life sciences, so make sure that

we're moving all these policies together.

So you have been a tremendous audience. Thank you so much for taking the time out of all your busy schedules to participate in this, helping us think about what we're doing. And with that, I will give you an extra 15 minutes to go out and wait in line for your taxi that Ryan has promised he's called all of you, and we look forward to additional feedback. Again, feel free to use that durc.ostp.gov. So thank you very much.

(Whereupon, at 4:00 p.m, the aforementioned meeting was adjourned.)

CERTIFICATE OF NOTARY PUBLIC

I, MICHAEL FARKAS, the officer before whom the foregoing hearing was taken, do hereby certify that the testimony appearing in the foregoing hearing was taken by me in audio recording and thereafter reduced to typewriting under my supervision; that said transcription is a true record of the proceedings; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this deposition was taken; and, further, that I am not a relative or employee of any counsel or attorney employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.

/s/ Michael Farkas

MICHAEL FARKAS
Notary Public in and for the
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August 6, 2015

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