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Note: Text has been edited for clarity.

Occupational Health and Safety Programs

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Slide 1 (Title Slide)

[Text related to information for attendees and submitting questions during original broadcast of the seminar has been removed.] Hello and welcome to the next in our series of OLAW webinars for [IACUC staff](#). My name is Jerry Collins and I will be the moderator of today's seminar entitled "Medical Support for Biomedical Research by Dr. James Schmitt. A PDF of Dr. Schmitt's slides is available in the [Education \[Resources\]](#) section of the OLAW website at olaw.nih.gov. Now it is my pleasure to introduce Dr. Jim Schmitt the Medical Director of the Occupational Medicine Service at the National Institutes of Health.

Dr. Schmitt earned a BS in Biology from Washington and Jefferson College and an MD from the University of Pittsburgh and an MS in Environmental Health from George Washington University. He received clinical training in internal medicine and dermatology and he is board certified in Occupational and Environmental Medicine. Dr. Schmitt joined the NIH Occupational

Medical Service [OMS] in 1982 as a staff physician and became its Director in 1990. He coauthored the Occupational Health chapter in the BMBL 5th edition and has contributed to publications defining occupational health and safety standards in the care and use of research animals and nonhuman primates.

Good afternoon, thank you for the introduction. I would like to start off the presentation by mentioning that I've taken the liberty of narrowing the focus of my presentation from health and safety to simply medical support for biomedical research.

Slide 2 (Overview)

First an overview of the presentation, I've divided it into four sections. The first is a single slide that identifies the relevant guidelines that inform the medical services provided for biomedical research. That is followed by some background information on occupational medicine to help explain the services offered in a biomedical research setting. Because occupational medicine services are ideally tailored to the needs of an organization, I'll then describe the NIH as a customer in need of occupational medicine support. Finally, I'll close with a description of the occupational medical support we've designed and implemented for the NIH community. Please note that this a description of what we're doing here and should not be taken as guidance for what another facility may do to elect similar needs at their location.

Slide 3 (Guidelines and Regulations)

So, the first issue of business then would be the guidelines and regulations. This slide includes documents that are cited by AAALAC. Please note that OLAW has not officially sanctioned the 2011 *Guide* [at the time of

broadcast]. So, for the sake of PHS assurance and OLAW, we are still held to the 1996 *Guide* standards. Other documents of interest to the provider of medical services include the Americans with [Disabilities] Act and a reference to OSHA regulations is included on this slide. What's not shown here is a reference to HIPAA or the code of ethics for occupational medicine providers both of which are relevant to this presentation.

Slide 4 (Medical Support Services: the Basics)

Let's get on now and talk about the basics of medical support services. First, the purpose of occupational medicine is to promote a safe and healthy workplace through the provision of work-related medical services.

Slide 5 (Purpose/Recognition)

At the beginning of this presentation, I would like to state that occupational medicine is just one more support service. Occupational medicine needs to balance the needs of the employee and their rights against the needs of management. The provider must be able to demonstrate respect for those that they are seeking to support. The importance of earning and maintaining the respect of those we're trying to help cannot be overstated. If a worker who is introduced to the occupational medical service provider concludes that either they are difficult to access or is poorly informed, he or she is less likely to seek assistance in a timely fashion...[inaudible]...highly recommended. From my perspective, there are two different approaches to the provision of these services.

Slide 6 (Alternative Approaches for Medical Support)

I've entitled one of them occupational medicine and the other employee health. In occupational medicine, services are typically tailored to meet the needs of the group and may include emergency medical care and health

promotion. They tend to be more focused on actual needs. It can be a very challenging requirement to keep them current when things are as dynamic as they are in a research environment. Employee health has a more expansive, perhaps less tailored approach and includes a wider range of non-emergent, personal health care services.

Slide 7 (Prevention)

Prevention as a general field is divided into three sections: primary, secondary, and tertiary. Primary is basically the avoidance of an injury – do that by removing the hazard, utilizing barriers, perhaps training. It's the most effective way of reducing the likelihood of injury – that is removing the hazard and barriers is the secondary thing, training is the least effective. Secondary prevention is the early detection and treatment of an injury. That's the focus of occupational medicine. To some extent occupational medicine is also involved in counseling and therefore could be seen as also providing primary prevention. Tertiary prevention is minimizing the long term sequela of an injury. So, where does occupational medicine fit into an organization?

Slide 8 (Where does this group fit in the organization?)

And, the answer is any of the options that are on this next slide. Which include environmental health and safety, student health, or facilities as well as human resources or contracted and off-site, would work. Regardless, the service needs to be readily accessible to employees.

Slide 9 (Essential Partners)

Essential partners for any occupational medical provider are first and foremost the safety specialists who help alert folks in occupational medicine as to what's going on in a work environment. Investigators and subject

matter experts are also useful as are the veterinary and human resources. Facility management is sometimes useful. Employees are a vital source of information. Senior management is especially useful. Without their support, it would be difficult to have this service be as effective as it needs to be.

Slide 10 (Understanding the Environment)

The provider needs to have an understanding of the environment. You can get it from interaction with the partners that I just described, from a general description of the workplace, and the hazards and research efforts underway. Also, there is relevant literature in the committees of the organization. Sometimes they are useful.

Slide 11 (What is "Medical Surveillance"?)

I would like to spend a little bit of time discussing the term "medical surveillance". This is a point that I would really like to emphasize in this presentation. It is mentioned, I should say without definition, in each of the NRC publications and also in section 5 of the BMBL, the biosafety level criteria for vivarium research facilities. However, the phrase is noticeably absent from section 7 of the BMBL, which addresses occupational health and immunoprophylaxis. I have attempted to define what I mean by medical surveillance on this slide. Medical surveillance is a careful monitoring to detect early clinical evidence of injury and permit early treatment, and thereby prevent further injury. Anything that appears in this presentation, which I consider to be primarily my opinion, will appear in green. So the next item is the medical support services for biomedical research rarely meet this definition.

Slide 12 (Medical Surveillance Requirements)

From the perspective of an occupational medical provider, medical surveillance has a definition; it must meet the following four elements. First, it requires a test that is reliable, acceptable, sensitive, meaning that it's not going to miss actual cases out there that you want to catch, specific, meaning the cases that you do catch belong in that group, and finally, capable of detecting an injury in time to make a difference.

Slide 13 (Medical Surveillance Requirements (cont.))

The second element is a plan for systemic collection and analysis of the resulting data from that test. Third, the provider needs to have an understanding of the prevalence of the finding in the community being served. That is the background noise. Finally, there should be a strategy for communicating the results of this analysis in a timely fashion to those with a need to hear of the information.

Slide 14 (Medical Surveillance Requirements (cont.))

Sticking with medical surveillance for just a second. In the 2011 *Guide*, there are three references that could be taken to mean surveillance, although the first does not use that phrase. It states that, "Periodic medical evaluations are advisable for personnel in specific risk categories. For example, personnel required to use respiratory protection." Periodic medical visits does not honestly constitute surveillance in that there's no test that meets the criteria that I mentioned earlier and an understanding of the occurrence rate in the community at large. Periodic medical visits are likely warranted for individuals who are working with BSL-3 and BSL-4 agents. The statement that personnel who need respiratory protection should periodically go back to see the physician or medical provider is again inaccurate. The periodic questionnaire needed for respiratory fit testing can be administered

by the person doing the fit testing. There are five simple questions, if the response is positive to any of them, then the individual could be referred to the medical provider for more detailed discussion. So technically, you don't need to go see a medical provider to be fit tested periodically.

The second statement in the *Guide* is "the medical surveillance program should promote the early diagnosis of allergies." Again, going back to the definition for what is medical surveillance, there really is no test that the work group is going to find acceptable that you are going to do that is a skin test or something else to see whether or not someone is allergic. You could ask a history but that could be handled just as easily by letting people self report once they've been informed of what the symptoms are – what the earliest evidence is – of an allergy.

The third reference is "Zoonoses surveillance should be part of an occupational health and safety program." It goes on to say that those working with nonhuman primates "should be screened routinely for tuberculosis." I agree with the statement, the test that is being used here is either going to be a serologic test or a skin test for tuberculosis, however the purpose of this screening is not for the benefit so much of the employee as it is for the primate colony. The reason is that primates are difficult to diagnose when they have TB and there's no effective treatment. The consequence is going to be you are going to need to euthanize in all likelihood that animal and quite possibly other nonhuman primates sharing the space. So the only real medical surveillance that goes on is TB screening, and that's again only for folks who are going to be working with primates.

Slide 15 (Confidentiality of Medical Information)

Here are a couple of other basic points. Occupational medicine is analogous to public health in the workplace, and like other medical practices occupational medical providers are required to maintain the confidentiality of workers' medical information. One way of considering occupational medicine would be to think of it as public health in the workplace. The provider has a dual responsibility both to the employee/patient and to the employer or the public. The intent here is to provide care to the individual while safeguarding the workplace to make sure that it is safe for others. In the process of providing this information, the occupational medicine practitioner must be careful not to share the employee's medical information but instead provide information on that individual's functional restrictions or things that they can't do and how long that will last, as well as conveying circumstances of injuries that could be used to make the workplace somewhat safer.

Slide 16 (Medical Evaluations and Services)

So then quickly I would like to go over the medical evaluations and services just in broad brush stroke, what constitutes medical care. There are preplacement medical evaluations, there are routine periodic medical evaluations, and there are for-cause medical evaluations, which would include the care for work-related injuries and illnesses and the evaluation of individuals either because of personal injury, illness, or intoxication, may not be capable of performing their job safely. The next slides we'll get that in more detail because I thought the subject may be of interest to the audience here, I have also added a little bit of information on serum storage.

Slide 17 (Preplacement Medical Evaluation)

So, preplacement medical evaluations are a medical visit that occurs typically after a job offer has been made but before the individual has

actually started performing the duties of the position. One of the common fallacies in occupational medicine and providers is that the performance of a rote physical exam could potentially be useful as establishing a baseline to compare future evaluations to. In fact, a rote physical exam does not offer sufficient value to make it recommended.

These evaluations, however, are very useful if the time is taken to discuss with the worker what exactly they are going to be doing. And at the same time, get information on that individual's personal medical history and immunization history. To describe the first aid and emergency medical care and how it could be accessed after hours. To provide the individual with work-related immunizations. And to offer counseling that will be relevant to their work activities as an employee.

Slide 18 (Routine, Periodic Medical Evaluations)

Routine medical evaluations, in general, these also are of limited value, and generally not warranted. A case could be made for offering them to individuals who work with BSL-3 and -4 agents and toxins; however that would be an exception to the general statement.

As I mentioned at the outset of this section, the occupational medical provider needs to demonstrate respect for those he or she is seeking to support. If there isn't a clear value to recalling workers for another medical evaluation, then we shouldn't interfere with their work by doing so. Concerns with allergies, pregnancy, and immune-compromising conditions should be addressed in routine training for individuals who work with research animals and human pathogens and they should be advised and to seek or report, self report, to occupational medicine and make the process of doing so as simple

as possible. But to recall them annually to ask them those questions is not necessary.

Slide 19 (For-Cause Medical Evaluations)

For-cause medical evaluations: all suspected occupational injuries must be reported. This is actually a very important point and should be stressed. Not only is it important for maintaining a safe workplace – OSHA General Duty Clause – the need to report all injuries on your OSHA 300 log and to safeguard the individual's potential right to workers' compensation benefits, but more importantly for the work group. If you don't know what's gone wrong, then you are at risk for having a similar problem with a much worse outcome at a future point. Personal injuries and illnesses that compromise a worker's abilities to perform occupational duties safely is another reason for periodically seeing individuals on a for-cause basis.

Slide 20 (Serum Storage)

Finally serum storage: the routine storage of serum is rarely useful. An exception again can be made for folks who are working with BSL-3 and BSL-4 agents. Much more valuable, is serum stored at the time of an injury report in which a potential biohazard was involved in the accident. The initial specimen is referred to as the acute specimen. And 6-8 weeks following that event, you should have the individual back and get an additional serum sample, the convalescent specimen. These specimens when tested simultaneously can provide valuable insight into a potential occupationally transmitted illness.

Slide 21 (The NIH as a Customer)

So now I'd like to move on to the third part of the presentation and this is the NIH as a customer. I want to emphasize again two points. First, that the

services, the occupational medical services, that an agency receives should actually be tailored to what they're doing. And secondly, the services I'm about to describe are services that I and others have helped to design for the NIH. They should not be seen as direction, but simply the approach our organization took to meet this issue.

Slide 22 (The NIH)

So let's take a look at what we're doing at the NIH. First, what is the NIH? It's the world's largest biomedical research facility. Here I've listed the mission and a brief description of how it's organized. There are 27 separate institutes and centers. Many people do not realize that the I in NIH is plural. I frequently refer to them as multiple fiefdoms on a common parcel of land, all with their own wards and vassals. Trying to keep straight who's who is a challenge.

Slide 23 (The NIH (cont.))

NIH has a very large budget, 31.2 billion dollars. The majority of this, 80%, is awarded via competitive grants to more than 325,000 researchers at more than 3,000 universities and medical schools, and other research institutions. The NIH holds on to about 20% and half of that is used in support of animal research activities by 24 of those 27 institutes and centers. The NIH is located in multiple locations. In Maryland they have the principal facility, the main campus is in Bethesda, but there is also an animal farm in Poolesville, Maryland, and operations in both Frederick and Baltimore. We have out postings in Montana and North Carolina, and numerous field stations.

Slide 24 (The NIH (cont.))

The NIH has a large workforce. Total of 37,000 people are badged to work at the NIH. On any given day, 22,000 of those people will be on the main

campus. More than 20% of the workforce holds at least one doctoral degree, approximately 20% of the NIH workforce is foreign born and there's approximately a 10 to 20% turnover per year, which makes it a very dynamic workplace.

Slide 25 (The NIH (cont.))

The NIH used in 2010, 1.7 million animals in research. 86% of them were rodents. Less than half a percent were nonhuman primates. The NIH has over 125, probably closer to 140 human pathogens that are being studied currently. There are somewhere between 2,500 and 3,000 laboratories. Approximately 25 of those are BSL-3 labs and eight are BSL-4, not all of those BSL-4 labs are currently operational.

The Animal Exposure Program, which I'll describe in a minute, and the business about the laboratory share something in common. Although a very small percentage of the total animals used are nonhuman primates, they are a very large draw on the medical services which I'll describe in a minute. The same holds true for laboratories. These BSL-3 and -4 laboratories constitute less than 1/8th of one percent of all of the labs at the NIH, yet the effort that they require for medical support is far more than is provided for all of the other laboratories.

Slide 26 (Medical Support at NIH)

So now that I've gone over the NIH as a customer, what I would like to do is describe for you what the medical services are here at the NIH that supports them.

Slide 27 (Medical Support at NIH)

So first of all, the medical support follows the occupational medical model as opposed to the employee health model that I mentioned earlier. We design, implement, and reassess services intended to address occupational health concerns of the NIH community. The Occupational Medical Service is a component of the Division of Occupational Health and Safety, and is part of the Office of the Director at the NIH. We service all of the institutes and centers and try to attend to their needs. All federal workers are eligible for care in the Occupational Medical Service. Contractors are limited in terms of what they can get. They receive care for medical emergencies and work-related injuries. They receive unique services such as the anthrax vaccine and the Biological Surety Program, which I'll discuss in a bit. And recently it was decided that they would also be receiving flu shots.

Slide 28 (Medical Support at NIH (cont.))

The staffing for the Occupational Medical Service, includes two physicians and a third physician who works a few hours every other week, he's an allergist. We have four mid-level providers; physician assistants and nurse practitioners. We have eight nurses, a half-time physical therapist, a full-time laboratory technician, three counselors, and a workers' compensation specialist. We have clinics located in Bethesda, again the main campus, in Frederick and Baltimore, also in Maryland, and in Montana. I should mention that the BSL-4 laboratories are in Frederick and Montana which explains why it is that we have a nurse station there. The clinic is open from 7:30 until 5:00 and we operate an on-call service for life threatening injuries and illnesses with some redundancy. There is always two people on-call. One of them may be a mid-level provider, but the second person on-call is always going to be a physician. The service has been used fairly frequently. We maintain a consultation relationship with numerous

infectious disease specialists to help us sort through unusual experiences. I should also mention that we are privileged to have a customized computer support program which permits us to not only work more efficiently, but generate a number of reports and notices to others, which I'll touch on in a bit.

Slide 29 (Medical Support at NIH (cont.))

So the Animal Exposure Program [AEP], as an acknowledgment to the fact that this offering does not meet the definition of medical surveillance, the S was removed from this a few years back. The program used to be known as the Animal Exposure Surveillance Program. Now it's simply the Animal Exposure Program. Federal workers with access to research animals or their living quarters must participate in this program. It gets back to the senior management being involved in supporting the medical service.

Because participation is mandatory, we have defined what are the minimum steps an individual must take to be deemed compliant. We have subdivided the program by types of animals contacted; small, large, nonhuman primate, and viable nonhuman primate tissues. Enrollment and compliance are reported online and in real-time. This is part of that computer application that I mentioned. Each of the institutes and centers have individuals who have been designated with the right to view who is and is not enrolled and whether or not they are compliant, whether they are meeting all of the requirements of the program. The program applies to approximately 5,000 workers at the NIH. Most of these workers are contracted and receive this service or a comparable service through providers in the community.

Slide 30 (Medical Support at NIH (cont.))

The AEP goes on to provide additional services for individuals who work with large nonhuman primates and nonhuman primate tissues. But here what I've described hopefully in this slide are the elements that are applicable to individuals who are enrolled in the program regardless of which animal type they are working with. In each and every case, we review the position responsibilities as well as the individual's medical and immunization history. If the individual needs a tetanus booster dose, we provide it. Other occupationally indicated immunizations are also provided. But the heart of the visit really is the counseling. We discuss at some detail allergies that can be associated with exposure to animal proteins and their dander, urine, or saliva. We discuss zoonoses as well as agent and toxin – provide agent and toxin specific information. In each case not only do we provide the counseling, but we also give them handouts that go over some of the information because the amount of material reviewed can be somewhat daunting. It helps to be able to look back and read over that. We highlight for individuals that there is a requirement to report all work-related injuries. Does not matter if they are an employee or a contractor, we must hear about the injuries. We discuss with them what is first aid, how they are to administer it at the workplace, and then what steps they need to do to access emergency care for occupational injuries and illnesses at any hour of the day.

Slide 31 (Medical Support at NIH (cont.))

This slide addresses some of the additional services that are available to folks who work with other than small animals. Individuals, women who are of child bearing capacity and work with cats are offered testing for toxoplasmosis if they do not already have serologic evidence of protection. If they don't have protection, then we provide them with appropriate

counseling. Individuals who are going to be working with nonhuman primates are screened for rubeola and if they do not have protection, they are immunized. This is a point that is missing from the ILAR guidelines on the care and use of nonhuman primates. We also enroll them in a TB surveillance program and provide them with wallet cards that address the possibility of their working with macaques and B virus and how they should be cared for. We also provide information on how to reach the OMS on-call service. Finally, individuals who are working with tissues from nonhuman primates may voluntarily enroll in the TB surveillance program. It's for their benefit, that portion of the program is not mandatory. So the only recall for folks who are enrolled in the Animal Exposure Program is for TB surveillance. It only applies to individuals who do not have evidence of prior infection and the testing is annual.

Slide 32 (Medical Support at NIH (cont.))

So here then are other relevant services for folks who work with animals; one is an allergy clinic, second is again the care for work-related injuries, and finally, I have thrown in something that's relatively new, Biological Surety Program. First allergies, there's no genuine medical surveillance for allergies. We rely instead on the counseling during the enrollment visit as well as annual training provided both by the work group as well as the Division of Occupational Health and Safety. Following the training, we rely on individuals to self report their injuries and allergies. If an allergy is reported, we have again an allergist who can perform the evaluation. I would like to digress here for just a second and highlight why it is that I believe that relying on individuals to self report works.

I have a rather large body of data for injuries involving exposure to human blood and body fluids over the last 21 years. I have an excess of 3,000

injuries. The median time to report an injury – we have a similar approach of counseling on the front end, signs in the workplace, and required annual training – the median time for reporting an exposure to human body fluid at the NIH is 20 minutes. The median time regardless of the day it occurs, whether it's a holiday or a weekend or the clinic is closed, to providing appropriate care, and our care is guided by consultation with infectious disease specialists who specialize in the care for individuals with H.I.V. infection, the median time for the last 21 years for us to initiate post exposure prophylaxis has been 90 minutes when the goal is 120. This system does work.

Slide 33 (Medical Support at NIH (cont.))

So then the next slide addresses care for those work-related injuries. It really is important that all injuries be reported. This is a possibility, a unique possibility for management to discover when things aren't working right so that they can take the necessary steps to make improvements and reduce the risk of further injury to someone else.

Every injury that's reported to our clinic is reported using that same computer software application that I mentioned to safety specialists which are assigned to each of the ICs [institutes/centers]. If there's an injury that involves a nonhuman primate body fluid or other substance of significant concern, in addition to electronically notifying them, the occupational medical provider calls our safety specialist and identifies the case and the need for prompt investigation to find out what went wrong. In our setting the Occupational Medical Service provides 80% of the care required for work-related injuries. In addition, we also provide care to contractors for injuries especially if they are somewhat exotic or it's less likely that they are going to receive everything that they would need in the community. In fact

we have creatively defined the word emergency to include any and all follow-up care for injuries that we would be concerned that there could be a risk of infection and you could not get care in the community. So for H.I.V. we provide all of the counseling, the treatment, the follow-up, including serological testing, and other testing. We monitor individuals for an entire year. For potential exposures to B virus, we provide similar services and the care goes on for at least two months.

We track all injuries that have the potential for being life threatening. This is something that was learned from the Yerkes experience some years ago. When an incident happens, I have somebody on staff who is designated to track a certain type of injury. Say injuries involving nonhuman primate body fluids or another person to track injuries involving human body fluids. We want to make sure that we collect all of the information that we are going to need on the front end to make a decision and that we don't lose track of the injured individual. We also provide in those sorts of cases numbers for the injured party to reach the medical provider after hours. So we give home numbers, cell numbers, we encourage them to call, make sure they understand that's why we're there is to help them. As I mentioned we consult with subject matter experts and infectious disease specialists rather liberally. One of the advantages of working at the NIH is we have a very large collection of specialists and they are all more than willing to assist when the need arises. Finally, where injuries are concerned, we plan and drill for incidents involving BSL-3 and BSL-4 agents. I'll get into that more in the next slide.

Slide 34 (Medical Support at NIH (cont.))

This is the final slide of the presentation; this is the Biological Surety Program. It is modeled after a program started at the Army. And again this

is one of the few offerings in occupational medicine where participation is mandatory. In this case, it's offered not just to federal employees, but also to contract workers. In either case, what they need to do to be deemed eligible for the program is have access to select agents and/or toxins in a designated facility or unrestricted access to the critical infrastructure of a designated facility.

Compliance is monitored and reported to supervisors, the periodicity for follow-up is annual. And the program is designed similar to the Animal Exposure Program in that there's a hierarchy with common services being offered to all, and in this case, BSL-3 would be analogous to small animals in that they get the basics. Folks who have specific agents they're working with get additional attention, informational handouts and counseling that address those hazards and the earliest signs and symptoms of infection and how to manage exposures, how to reach us after hours, a wallet card, and immunizations where they are available. BSL-4 involves all of that with the exception of immunizations, because there are no immunizations for BSL-4 agents. Instead we go over with them – what we're going to be doing in the way of care, which could involve the transportation to a hospital for monitoring. We also do psychological testing and safety testing to make sure that the person is up for working in a suit and in that environment, and we also do a cardiac risk assessment.

Underpinning this general program are agent-specific procedures for select agents and toxins. And as I mentioned in the last slide, we have annual drills, the drills involve scenarios with potential injuries and illnesses, and involve folks that work in the laboratory, some of these drills are announced and some are not. The drills also involve folks from health and safety, the

folks who are doing the transport as well as the medical providers, and the hospital services that they will receive should they need to be hospitalized. It also involves notification for the intramural NIH staff and the public affairs office so the questions can be answered in a timely and appropriate fashion.

The one point that I think I would like to emphasize with occupational medicine is just like safety. The most important thing is to think ahead, to first do a risk assessment, know where the hazards are, at least where you suspect they may be. And then develop a strategy for what you are going to do when the efforts that you have taken to prevent exposure don't work and somebody has an incident. Exactly how is that going to be handled, from notification of the provider, to what the provider does, and what the follow-up will be. And so the biggest effort here then is to know what's going on, think enough about it to develop a strategy that you have discussed with others for how you'll handle it, advertise it, and then practice it.

So that concludes my presentation and I welcome any questions.

Slide 35 (Questions?)

Thank you, Jim, and first of all, I want to apologize to you for the technical difficulties. I know that you've put a lot of time and effort into this presentation, and I feel very badly that it was disrupted to some extent. I am given the unenviable task of asking you, if at all possible, could we impose upon you to record this again as some date in the not too distant future. Our reason for asking is that there is a requirement that we have captioning available for this. Since the captioning broke down, what we would like to be able to do is rerecord this session. That would be the one that we would put up on the Web. So we can chat about that later on and see if your schedule will allow that. We will now move to questions. We have

about 10 minutes left. We won't go beyond our one hour time period, because we recognize that all of you who are participating have your own schedules.

1. The first question that came in from one of our participants is, **What constitutes enrollment in the occupational health and safety program? If someone has waived, does that mean that they are enrolled?** I'm not sure what is meant by the term waived. But enrollment involves the items that I have on that one slide where it talks about a discussion of what it is the worker will be doing. A description of the hazards and handing out information related to them, updating the tetanus booster if needed, and telling them how to deal with the first aid issues. Once they have been fully informed and they've received the basic services, they are enrolled and they are participating.

2. The next question has to do with measles and primates. It asks. **If confirming measles immunity is a way of safeguarding primates.**

I'm sorry, can you repeat that?

Confirming measles immunity to safeguard primates. Yes, it's definitely to safeguard the primates. Measles is a bigger issue for New World monkeys than Old World monkeys, but it is a zoonoses that can be transmitted bidirectionally and is extremely infectious.

3. Here is another question that just came in from our participants. **Many institutions TB test employees that work with NHP's [nonhuman primates] every six months. Has NIH always tested employees on an annual basis? If not, and the change was made from six months to 12 months at some point in time, what data was used to support that decision?** I think we spearheaded the every six month testing and we

changed that approximately two years ago, year and a half ago. And it was based on our own experience with testing thousands of people for over 20 years and finding only a handful of folks who were skin test converters. That coupled with our experience with the education and its value in getting people to self report, we felt confident that we could go to annual testing.

4. Another question that just came in from our participants. What are the options if an employee has been identified with allergy symptoms?

So the best predictor of who is going to have an allergic reaction to animals, laboratory animals, would be someone who is already allergic to cats or dogs. If an individual comes to work with an understanding that they are allergic to animals, that happens actually fairly frequently, I would say more than half of the cases that we pick up are individuals during the preplacement exam that tell us during graduate training or whatever, they have already been aware that they've got a problem. The first thing that we do is counsel them that continued exposure is potentially risky to them in that if you are exposed long enough, you may end up with persistent asthma, even when you are no longer exposed to the allergen. We highlight for them the importance of the protective measures that are part of the safety training. Depending upon the severity of the reaction, we may advise them to consider other work that would not involve using those animals. In very rare cases, the Occupational Medical Service will recommend that the individual not be permitted to work with animals. And that's a rather high standard to meet. Typically what we use is if the individual has had a prior anaphylactic reaction presumed to be due to exposure to animal proteins. And we have seen several cases like that.

5. Looks like we have a couple of other questions about allergies, one of them related to evaluations. Along with initial counseling and self

reporting, do you have employees fill out an annual allergy questionnaire? In addition to that, is the training and counseling enough for allergy assessment? So, do we have people fill out an annual questionnaire? The answer is no. Is training and self reporting sufficient? I know that when AAALAC visits, they have expressed concerns at each of the last three visits at this approach. However, I believe given our experience with other hazards, and our experience with individuals self reporting, that it is effective. And if you have 5,000 people who work with animals, suggesting that they all fill out the same questionnaire or a similar questionnaire for years and years and years, especially when the occurrence of allergies is a sort of front end loaded experience, I think undermines the confidence of the folks that you are trying to serve. If you instead treat them with respect, provide them with appropriate training, perhaps involving a question and answer session at the end or even a quiz, I think that you can achieve the same goal without having them fill out the same questionnaire that they fill out year after year.

6. Here's another question that came in. It goes, **How would you recommend that we handle individuals who need to enter facilities where animals are housed or used – no direct exposure? Is a signed waiver form okay?** They describe the different groups as contractors or subcontractors, not directly affiliate with the institution, service contractors coming in to fix autoclaves, things like that, or the non-affiliated IACUC member who does participate in semiannual inspections.

The approach taken by the NIH is the responsibility of deciding who needs to be enrolled in the Animal Exposure Program. And if the individual is going to access the facility and not be enrolled in the Animal Exposure Program, what steps they need to take to safeguard their own health and the health of the

animals that they are visiting. That decision is made by the facility manager in consultation with the veterinarian responsible for that group. If they decide that enrollment in the AEP is warranted, we provide the medical service. But they decide who should be enrolled.

7. We have about maybe two minutes left, Jim, so we will do one or two more questions. **Is it okay if personnel go to their own doctor to seek relevant medical support services for animal related issues?** So, I believe that this again is a workplace specific decision. I think that you can receive the routine services from outside providers. The one thing that I think should be stressed is the need to capture data on work-related injuries and illnesses centrally. So if you have a provider who is on-site, that makes it easy. If you have folks who are off-site, you have to stress, either in general counseling or in a boilerplate language for your contracts, that information related to injuries needs to make it back to the parent institution.

8. And two remaining questions. The next to the last one, **What type of role or collaboration does your medical surveillance group have with the IACUC? Is the medical group involved at the protocol review level with the IACUC?** The NIH again is extremely large and – and the way we get the benefit, the economy of scale, in our case our safety specialists, which are part of the same division, occupational health and safety, sit in on the protocol review and are mindful of the occupational medical needs. So we do not have somebody from the Occupational Medical Service sitting on these committees, but there are safety specialists that sit on them and represent OMS in the process.

9. Final question concerning the care of the NHP's, it says, **Since the purpose of the TB testing is to provide protection for them, why is it that the personnel working with the animals are able to voluntarily determine whether or not they will participate in the TB testing?**

Well, TB skin testing is not voluntary for anybody who wants to work with nonhuman primates at the NIH. The value and testing is you want to detect someone who could be potentially infectious to others, that is has active pulmonary or laryngeal TB. The risk to the nonhuman primates is that there is no effective way to treat them. The consequence is most likely the demise of the animal and perhaps other animals in the same facility. We do not permit people to opt out of TB skin testing if they had not previously demonstrated as having been infected and are no longer a risk to others.

Jim, thank you again for taking time from what we know is a very busy schedule to participate in the seminar series, we are truly grateful to you for it. Also grateful to all of you, the participants, who have participated in this and other of our seminars series. We definitely appreciate your feedback and take your suggestions seriously. You will receive an e-mail from us tomorrow. Currently we are planning webinars for 2012 and 2013. If you have suggestions for webinars that would be useful and interesting to you, just send them to us in a return mail. We certainly are glad that you joined us today, and we look forward to our next webinar which will be on Thursday, December 8th. That webinar will be on the topic of Grants Policy and Congruence, the speakers will be Dr. Pat Brown, OLAW Director, and guest speaker Tina O'Neil Hudson. For those of you from institutions where your Institutional Official listened in earlier today to the IO webinar, I mistakenly said that the date would be Thursday, December 7th, it is December 8th. Thank you very much. And for everybody here at OLAW, we wish you a pleasant fall season.