John Balog: For you to demonstrate compliance with the guidelines and directive. Well, VHA directive 1200.08(1). And then describe the steps of the NIH IBC Registration Management System registration process. Next slide please. Okay, there we go. So we’re going to review here the three previous webinars. I bet there highlighted some of our previous objectives just to reorient us to where we’re going here as a biosafety and bio security program. We introduced the program, we summarized the activities data calls, et cetera. And described and rolled out some educational tools that are available on our website. We discussed in the webinar too, the foundations of the program. Risk. Risk. Risk. Identification, assessment, and management. And then the third webinar we defined what the IBC is, what it does, and so common challenges that we’ve encountered through our outreach and communications from the field. And we discussed and propose solutions to some of these common challenges. Next slide please.

And today we’re going to primarily focused on section IV-B of the NIH guidelines with institutional requirements. Chief among them is VHA directive 1200.08 and that some general information, as well as particularly here the IBC membership, the procedures, and the functions. Next slide please. So according to our VHA Directive 1200.08(1) paragraph 7a. If your station intends to permit conduct of any research falls under the scope of the guidelines involving research involving recombinant and synthetic nucleic acid molecules, you have to establish your own IBC. And that would be an internally administrated IBC. Or obtain the services of another VA facility’s IBC or obtain the services of an academic affiliate IBC. In those instances, the IBC is externally administrated. ORD policy does not permit the use of commercial IBCs. Next slide please.

So is a nonprofit corporation required to have IBC approval? So when the associated VA facility conducts VA research requiring IBC approval according to the NIH guidelines. Next slide. Okay the scenarios here are that the nonprofit corporation is the administrator of federal funding or is an awardee. The nonprofit corporation is an awardee institution and so in both of those instances, the answer is yes. Next slide please. So you can establish or administer your own internal IBC or rely on external IBC. And these are the two options for an externally administrated IBC. Next slide please.

So the requirements for committee membership. There’s an appointment of at least five voting members. There’s no limit, but typically want to allow your membership to meet the program needs with regard to expertise and the volume of work that you’ll be through putting the committee review. You must identify a chair, an NIH contact person, and when working with large volumes of regulated materials, a biosafety officer. And if you’re using a—as well as when you’re using a BSL-3 laboratory. And if you’re using animal models under high or maximum containment, you want to have animal containment expert on your committee. And these will comprise your roster. And you require CVs, curriculum vitae; resumes or bio sketch. Those are equally valid of the members and use those to register the IBC in the IBC record registration management system. That’s a typo there. That should be registration management system. Next slide please.

Our directive states that an internal IBC may share membership with their subcommittee on research safety or be constituted as a separate subcommittee of the research and development committee. The IBC is responsible for reviewing research that involves recombinant synthetic nucleic acid molecules if the research is covered under section 1-C, general applicability of the guidelines. The IBC must meet all requirements for membership, review of research, and other activities as outlined by the NIH guidelines. Next slide please.

Now a word about documentation process and procedures. IBC governing the documents, charter, standard operating procedure, or other document requirements for the membership and review of research. So documentation of review and the vote on research proposals involving biohazard. And notification to PIs of the review outcome including the approval date, the biosafety level, and classification under section III of the NIH guidelines for work with recombinant or synthetic nucleic acids. Next slide please.

Okay, so a research program may use an academic affiliate IBC under the following conditions. That an MOU is negotiated for IBC services and that MOU outlines the responsibility of the VA facility and the academic affiliate in this arrangement. The NIH-OSP registration, first of all the VA facility establishes and maintains registration with the NIH-OSP and names the affiliate IBC as its IBC of record. That’s a critical designation. The NIH is aware of approves of these mechanisms to secure IBC services and supports this practice. And the MOU should as well have compliance with VA policies. The external IBC must review research in accordance with all VA policies and other federal requirements. Next slide please.

Documentation. The IBC meeting minutes and documents related to the review approval and oversight of VA research must be provided to the SRS, and R&D committees or the research facility office within a reasonable amount of time. And that’s described in one of the terms in the Memorandum of Understanding. IBC membership. At least one voting member of the external IBC must be a VA compensated employee. Of course to represent the interests of the VA and their station on that committee. Next slide please.

So paragraph 7e of VHA Directive 1200.08(1), a VA research program may use another VA facility’s IBC subject to the following. That IBC must be an internal VA IBC. It cannot be a secondary or tertiary under MOUs. But also, that committee must meet the NIH requirements for community representation. The word on that, the NIH requirement for community representation does not specify a geographic region. They say it should represent the community. So it’s a practical matter on verbal communications with the NIH-OSP. They will not put this in writing, but their working definition of an appropriate geographic range is dependent upon the location of where the IBC is.

For IBCs at institutions or entities in an urban area where you’ve got a certain population density, they have a rather 10-to-25-mile radius in which they will accept community members as being eligible. And in rural areas where you’ve got lesser population, they’re more liberal. For instance, they’ll accept up to a hundred-mile radius for an acceptable community member on the IBC. The IBC must also be knowledgeable regarding the requesting VA facilities. The membership that VA compensated employee from the requesting facility must be appointed as a voting member of the IBC. And it’s the requesting VA facility that establishes and maintains registration in the NIH-OSP IBC RMS. Naming the affiliate VA IBC as its IBC of record. I’m sorry. I misspoke there. With the second VA station IBC as the IBC of record. Next slide please.

Now roster. The roster document. Here’s a depiction of the preferred IBC format. Roster format. The example is up in the upper right column. You want the name, the academic credential, and title of the member, as well as their affiliation, and contact information, and their role on the committee. Be it the chair, the NIH contact person, nonaffiliated community member, and if applicable the animal containment expert, and biosafety officer. They also want a little blurb in there on their biosafety expertise and their scientific expertise. And they give examples of the techniques and processes and procedures and at what biosafety level the member is familiar with. And whether or not they used animal models. Whether they performed assay development or optimization and other similar techniques. There’s really no hard and fast requirement for these definitions. They could be as specific or as general as you care to enter. Next slide please.

Now registering and updating the IBC. Its’ presumed by the NIH-OSP that NIH IBC contact person listed on your roster will be entering this data into the system. And when you want to register, they’ve got tutorials here on the site to see the process and gather information. But I think we’re all familiar with the—to start an account. You click on the request access link in the upper right here and you’ll enter admin administration information and address and the name of your IBC, et cetera. And you’ll create that account. And you’ll go back at least annually thereafter to update your roster. And you need to login at least once a year to maintain activity.

And there’s a link in there were there’s no changes, but you will confirm that, and the date stamp will be added to that document in the system. For infrequent users, use the tutorials to refamiliarize yourself with the system. And there are a number of phone numbers and emails out there on the NIH-OSP website to contact them. But for IBC matters, I recommend that you use the contact us under the support banner in the lower right corner of the depiction of the IBC Registration Management System website. That way you will generate a record of the discussion and you won’t have to—it’s a lot easier to retrieve conversations that way. Next slide please.

Some tips. Your governing documents are not required to be uploaded into the system. For example, your charter, SOP, or other documents. That’s not part of your registration. The user password expires after three years and can be reset by the user upon expiration provided the user email address is not changed. Otherwise, if the contact person changes or if there is a change in the email address for the NIH contact person, using the forgot username or password will help you to reset the password. And note that the IBC administrator will respond to all inquiries submitted via the contact us link. And another point on that, by contacting the RMS administrator, you’re more likely to get an answer at the first communication rather than have your inquiry go to somebody who’s perhaps not familiar with your question and not in a position to answer your question. And forwarding it ultimately to the administrator for them to respond to you. Next slide please.

Okay. Per section IV-B-1-a, institution must establish and implement policies that provide for the safe conduct of recombinant or synthetic nucleic acid research and ensure compliance with the NIH guidelines. The institution may establish additional procedures as needed. So at the VA, we’ve got a number of publications and directives and guidance documents that are available. These are intended to support local procedures in the end conduct of IBC operations. But note the guidelines do not require an IBC charter. They’re very open-ended in that regard. However you choose to define your governing documents, you’re at liberty to do so. Next slide please.

VHA Directive 1200.08 does not specify or mandate the exact format of the local guidelines to be established. The directive does, however, state that procedures for a VA IBC review and approval of VA research must be described in local guidelines. Next slide please. So your facility will determine the type of IBC governing documents that it will use, whether it's BARDA or the administrative procedure or SOP or some combination of the two. Certainly the larger and more complex biomedical research program will usually have more administrative documents than smaller programs. For example, if you’ve got protocols using different viral vectors either in an animal model or not, those will involve more specific and greater risks to be assessed than \_\_\_\_\_ [00:19:11] in contrast with a site that has multiple protocols for conducting say genetic analysis of a human blood specimen. Next slide please.

So in your governing documents please do include an expression of support from the station leadership about the IBC oversight and approval of VA biomedical research that promotes the safe and responsible conduct of that research. A description of the VA charge to the committee to conduct the reviews of the recombinant or synthetic nucleic acid research under the guidelines and VHA Directive 1200.08. As well as the need to comply with safety program elements applicable to the research reviewed by the committee. For example, the laboratory inspections, the worker training, and if appropriate, medical surveillance of workers. Next slide please.

You want to define the scope of research to be reviewed by your IBC whether it’s going to be only recombinant or synthetic nucleic acid research covered by the guidelines. Or a percent per section for IV-B-2-b-(9) performing other functions delegated to the IBC. For instance, pathogen, infectious agents, and toxins in the absence of a recombinant DNA element or synthetic nucleic acid. And they also want to direct that the IBC coordinate its review processes with its sister oversight committees. The IRB and the Institutional Animal Care and Use Committee when review of those committees is required of the research. Next slide please.

NIH guidelines section IV-B-1-h. Ensure appropriate training for the IBC chair and members, biosafety officer, and other containment experts when applicable as well as the PIs, and laboratory staff regarding laboratory safety and implementation of the NIH guidelines. Next slide please. ORD created an optional VA IBC member online training course on the Collaborative Institutions Training Initiative platform. The CITI program. And you can access it there. And this information is also on the reference slide at the end of this presentation. The facility ACOS or Administrative Office for Research and Development may contact Dr. Alice Huang via email to make the course available to learners at your facility. Dr. Huang will also help with general questions about the course availability. And Alice is very fluent and helpful in that regard. Next slide please.

Additional documents. A copy of the registration submission along with the NIH Office of Science Policy email notice of acceptance and the initial and annual report documents. So it should be retained probably electronically, but some places do prefer hard copies. Keeping in mind that all these documents are subject to you, and you also want to have a copy of each members letter or notice of appointment. Their initial member training or however you orient the new members to the expectations for their role on the committee and the current roster of IBC members. You also want to keep copies of NIH reportable incidents, occupational exposure events, or environmental releases involving recombinant or synthetic nucleic acid if any. Note the terms for obtaining documents from externally administered IBCs are included in the VA to the affiliate as well as the VA to VA IBC MOU. Next slide please.

A word on the meeting agenda. Some required elements are highlighted with a star, but certainly the meeting date, start, and end times are required as well as the roster of members in attendance. And also note those voting members that are absent and guests if any. You want to list the protocol title, number, and any members declaring a financial or professional conflict of interest with review of that protocol. That’s an option by the way. You don’t have to do that. The list of protocols and amendments to be reviewed with the PI name, project title, primary IBC reviewer if assigned. And it’s also optional to include old or new business if any. Next slide.

The meeting minutes on the other hand must include again, the date, location remote or in person as well as the start and end times for the meeting. Again, the members present; voting members that is the absent and present as well as guests. And it’s good to have a statement that a quorum of members is present. And you should also have that defined in your governing documents what you consider a quorum of your members. And the safest definition that I’ve come up with a quorum is 50 percent plus one to make a quorum. Also, the minutes should contain the protocol title, the name, the primary reviewer name. And this is important. A brief summary of the work. A summary of the IBC discussion and the motion to vote or table the protocol.

And tabling has different meanings at different stations that I’ve seen. As long as your processes are defined in your governing documents and you have those that meet the VA requirements, you can call it tabling. You can call it whatever you like. And again, it is optional if you want to include new business and old business. And again, the optional issue speaks to what you are required to make available in the event of a public request for your IBC documents. There are instances or there may be instances where sensitive or proprietary information that has nothing to do with the review of the research that is being reviewed, so there’s no need to capture that information under the NIH guidelines. Next slide please.

The IBC may deem certain methods and materials eligible for an administrative review. Typically we’re talking about personnel changes. Things that don’t alter the risk assessment of the work. The procedure should not and must not conflict with VA handbooks or directives. The eligibility of a protocol for administrative review must account for worker training and annual lab survey requirements. And a note that nonexempt recombinant synthetic nucleic acid work described in protocols are ineligible for administrative review. Those must go to the full committee. The IBC protocol review procedure must not conflict with established subcommittee on research safety or research and development committee practices. Next slide please.

Some suggested items for review. A survey document of the laboratory and support spaces as required or as specified in the CDC NIH biosafety and microbiological and biomedical laboratories. The be BMBL as well as the safety training records for the PI and laboratory workers. The description of the propose research documents, the assessment of the risks associated with the biohazards, and methods proposed for use in the research protocol under review. The PI, you want to make sure that the PI is proposing a facility biosafety level and work practices biosafety level for their work with recombinant or synthetic nucleic acid research as well as their classification under section III of the NIH guidelines. Next slide please.

So in summary, using an internally administered VA IBC or an externally administered IBC is permitted under ORD policies in VHA directive 1200.08(1). But the IBCs must adhere to the NIH guidelines. There is flexibility in how governing documents are developed, but required IBC administrative documents include the roster, and the agenda, the meeting minutes, member training records, and locally generated governing documents. That concludes the slide set of this presentation. At this point we’ll open it up for questions. Thank you very much. One more. We got a reference slide. Next slide please. I’m sorry. Updates and reminders first.

We’ve recently published the template for IBC meeting minutes. You don’t have to use. It’s optional. But for folks starting out and you want a point a reference, that’s a good place to start. And please email us at the vhacoordbiosafety@va.gov for questions regarding research biosafety or biosecurity. Or please if you haven’t done so already, join the biosafety and biosecurity email distribution list. I’m getting ready to send another message out here shortly. You may also request the hard copy of the BMBL at this web link. Just some advice, please use your home mailing address. Multiple copies won’t be sent to the same street address, and they’ll only allow you to request one copy per addressed. Next slide please.

And here are some references. The NIH office of Science Policy. A lot of information on that site. I recommend you scroll through some of that. Certainly there’s repetition and maybe some more detail, nuance detail that perhaps wasn’t included in this presentation that you can extract from those resources. And of course the guidelines from April 2019 are listed at this address. And for VA biosafety and bio security policy, please see the VHA publications at va.gov as well as the VA ORD biosafety and bio security program webpage for updates. And again, thank you very much.

Moderator: We are going to be pulling your questions up on the screen if you give us just a moment.

John Balog: Question one. So even if my VA facility does not operate the IBC, I still have to enter and maintain the membership roster in the NIH system even though the affiliate or other VA also maintains it? The answer to your question is yes. This question has been asked in multiple iterations and the NIH has provided guidance on this. Your site under MOU is still responsible for the activities of that—to ensure the activities of that IBC with which you have an MOU is operating under the guidelines. The implications of that are, if there is any problem, any issue emerges, the affiliate IBC is not accountable. It is the VA site where the issue arises. So when that committee is acting to review the second VA site, so the entity providing the service is responsible to the facility requesting the service on the review of that requesting facility’s research. I hope that’s clear. Karen, can you phrase that a little more clearly perhaps?

Karen Jeans: I think you’ve said it. Hi everyone. My name Karen Jeans. I’m the Director of Regulatory Affairs here in the Office of Research Protection Policy and Education. So what John is saying is that, yes. It’s like hey, they have it. Do we have to do it too? Based on what the NIH Office of Science Policy has informed us, and this is not unique to VA is that, each party must have their own. And so yep, I absolutely understand the phrasing of the question. Hey, hey have it. We have to do it. And the word is yes. It’s like what John said. NIH wants both sites to do this.

John Balog: If I could. One other example, if I could further clarify this. If there’s an exposure or other reportable event, it is incumbent on the IBC, the site to report that. So your reporting mechanism under the IBC—and this should be spelled out in your governing documents as well as the MOU. If there’s a reportable event, it should come from the site where the event happened. Because where the event happened, that’s where the investigation is going to happen. So that information that will populate the report to NIH will come from the site where the event happened, not from the site providing the IBC services if that helps.

Okay, next question please. Where is the detail that the NIH contact person must be a voting member of the committee? They are not required to be a voting member. Typically, they are. But they are not required. So if I gave that impression, that was wrong on my part. Can you provide the reference that requires the primary reviewer to be listed on the agenda and the minutes? Okay, sure. The reference for that is going to be in the NIH guidelines under operations as well as your governing documents. You want to be clear on your committee’s operations as opposed to just saying in general, it was the committee’s consensus that X, Y, and Z. Next question please.

What type of OSHA safety training records are required? I.e. blood-borne pathogens. Very good question. Consider that OSHA considers the laboratory a hazardous workplace and where hazards cannot be removed, you have to have policies, procedures in place to mitigate those hazards. So your right to know training on chemical safety. Virtually every laboratory has at least some hazardous chemicals. And by the way, salt, NaCl has a safety data sheet with cautionary hazard information on it. So the record that folks are trained in, those requirements are required. And as you suggest here, blood-borne pathogens training as well as the annual refresher trainings.

And any specialized equipment that involves a hazard and virtually every or most pieces of laboratory equipment can pose a hazard. Electrical hazard. If you’re moving—for instance, if you’re doing ultracentrifugation, and this is from my own personal history. Those titanium rotors are very heavy. So lifting training was required by our safety program. So this is a—your safety program should be evaluating the hazards in the laboratory. Evaluating the hazards for the work that’s described in these applications and making determination on what’s the appropriate trainings. Anyone else have any comments or want to expound on that? Okay, next question please.

Moderator: That looks like our last one for the moment.

John Balog: Okay, very good. Very good. If I can now make a general statement about the—this is a career wide observation. There are a lot of administrative requirements related to research, biomedical research regardless of whether you’re at the VA. If you’re in the industry, your entity has policies and procedures you must abide. And the old adage that if it isn’t written down it didn’t happen certainly applies. And the question is, why is that? And what I’ve concluded for myself is that I look at everything I do from a legal standpoint. What happens if a third party comes in and asks me, what did you do? Why did you do it? Or why didn’t you do it? So what happened?

So all of these things we do, I want to be able to support an investigation of my activities. And when you think about it, when you look at a scientific publication and you see the description of the work, that’s intended to allow the reader who is qualified and trained and has the resources to be able to replicate what was described in that research paper. So that may not fit all and every aspect of what we do, but it helps me to preserve my focus. And so I just thought I would share that with you while I had the opportunity here. So with that, I have nothing else. Dr. Jeans, do you have any closing comments that you would like to make?

Karen Jeans: No. No, I very much appreciate this presentation. I hope everyone on the webinar has also enjoyed it and also there’s some really good questions. But I see there is an additional question that has been asked, so let’s see what the question is.

John Balog: What are the requirements of ORO review when the IBC is not within your VA MC? Do we need to provide minutes and documentation? Okay, so when the IBC is not within your VA MC, I’m assuming that refers to an externally administrated IBC. So if that’s the case, the terms of your MOU should provide for the servicing IBC administration whether it’s their research office or whoever is the secretariat for that IBC to provide those to you as the other party to the MOU. So you should have and maintain separate files on that IBC service that you are entered into an MOU to obtain.

Karen Jeans: I’m going to add to that if I may. Okay, so this is a good question. One of the things I was going to say is, we’re going to look at the questions that—and this is a new program by the way. And so that’s why this is so important to us. This is a question that we will also go back to the Office of Research Oversight to ask them because it is a great question is, to hone in on it and to get the answer from RO RSAW. As John has stated there are MOUs. And in the MOUs, it states what the external VA or the external affiliated university is required to supply to the VA facility it’s relying.

And so while we would think that is what probably RO is looking for, we do not know since we cannot speak for RO. So what we will do is follow-up for this question is indeed, get an answer to that from them. And then as John has referenced in the distribution list that he can utilize as one of the mechanisms to put in the distribution list. And also, as you know about FIND Pro, we’re populating with the FAQs that if we can ask RO if we could also making FAQs that we can put in the FIND Pro FAQ portal. So that is something that will be a follow up as part of this webinar. And we thank you for asking this question.

John Balog: Yes, all very good questions. And certainly if anything comes up later, I’m very poor at coming up with questions in the moment. But when I reflect on seminars I’ve attended, I generally come up with some questions. Please take advantage of the avenues you have. Our mission is one of communication. When all is said and done, when you talk about safety, one of the hallmarks of a good safety program and indeed of a high reliability organization is communication. So okay. Thank you again very much. I apologize for the delayed start. And have a great afternoon and a good evening.