Kate: Good afternoon everyone. And please give us a moment to share our slides. Alright. And it is now 2:00. Good afternoon everyone. And today’s webinar on the Press Ganey RN Survey. I’m Kate and I’ll be your administrator today. I’d like to go over a few reminders and housekeeping items. First, today’s session is in lecture only mode and therefore, the audience is muted. This presentation is being recorded. Handouts were sent out and emailed to everyone who registered, and you did not receive them, you can find them in the Q&A box located on the right-hand side of your screen. And I’m just going to pause here for a moment to give everyone a chance to find the Q&A box on the right-hand side of your screen, and the link to this presentation as well as the handout. You can make the Q&A box larger by undocking it. You can do this by double-clicking on the middle of your screen and then clicking and dragging on the corner of the Q&A box to make it larger.   
  
To return to normal view, you can just double-click on the middle of your WebEx screen. Questions will be addressed at the end during the question and answer portion. When submitting your question, please select send to all panelists. Please do not use the chat feature to submit questions. WebEx events does not automatically share your questions submitted with others. However, will share all of the questions submitted by replying to each question with the phrase, thank you for your question. If you have difficulties running this webinar, some people have had more success using Google Chrome instead of Internet Explorer. Also, if you experience connectivity issues, our live webinars can be accessed using the call in number that’s provided on the slide as well as in the registration confirmation email. With that, I will pass it along to Dr. Karen Jeans, Director of Regulatory Affairs.

Dr. Karen Jeans: So hi everybody. First of all, I’d like to confirm that you can hear me. So Kate, can I make sure that everyone can hear me?

Kate: Yes, we can hear and see you.

Dr. Karen Jeans: Okay. And so thank you very much for joining us today in this webinar, which is called Press Ganey RN Survey Research Study. This is a joint presentation between the Office of Research and Development and the Office of Nursing Services. I am joined here by a number of panelist including Dr. Sheila Sullivan, Dr. Don Workman, and other individuals from the Office of Research and Development and the Office of Nursing Services. What our plan today is to…the presentation should be around 30 minutes and then we’re going to allot about 30 minutes for questions. And so when we announce this webinar here in the Office of Research and Development, I instantly got a lot of questions.   
  
Why is ORD doing this? And so what I want to start out is saying, why are we even doing this presentation today? Why did ORD and ONS combine our resources to do this presentation to have this very important discussion today? Well, this started a few weeks ago when questions were raised by different VA facilities. Because there is no national contract with Press Ganey to conduct the NDNQI, which is the National Database of Nursing Quality Indicators. And there’s a component called the RN Survey. And so different VA facilities were contacting each of our offices differently with the same questions. ORD and ONS. Hey. By the way, is this RN Survey a human subjects research study?   
  
If many sites were doing this, why can’t we coordinate to get a national enterprise solution on different issues that are common to any VA facility that’s involved in the conduct of this NDNQI RN Survey? And as a result of numerous different questions and issues that we found, we coordinated our resources to identify and resolve including communicating with Press Ganey. And I want to make it very clear right now that this RN Survey, the NDNQI itself is very important to the agency. And we value the relationship and Press Ganey has been working very well with us and we value that relationship with Press Ganey. And so this is again, we’re all in this together.   
  
We all want to help each other and so that’s why we are coordinating so that different VA facilities don’t have to come up with solutions when we can indeed intervene at the national level to provide clear solutions, clear guidance on what needs to be done with this. So today’s webinar is going to discuss these type questions with strategies for VA facilities who are participating or plan to conduct…by contracting with Press Ganey the 2021 Press Ganey in the NQI RN Survey. So what we’re going to cover here…and again, we’re planning to do this for about the next 30 minutes. It’s very brief, it’s very important to discuss the background of the NDNQI. And then we’re going to talk and focus in on the RN Survey, which is a separate component of the NDNQI. I’m going to be using those initials a lot.   
  
We’re going to talk about the cons of the RN Survey is what it is. The research regulatory processes that we put in place and we’re also going to talk about some additional agreement review topics which are related to the NDNQI RN Survey. So as a matter of jumping in so that everybody…because we have a lot here. We have of course, a huge number of you VA facilities and different nursing offices, but we also have different research departments who are represented. And so, everyone doesn’t know what the NDNQI is. So this was established by the American Nurses Association in 1998 and Press Ganey Associate acquired it in 2014. Now it is an important tool that I just used. It is used by its client’s facilities and there are a number VA facilities that indeed do contact with Press Ganey to conduct the NDNQI to do unit level nursing quality measurements. Benchmarking.   
  
Now, that activity is not research and it’s very important. And again, a number of client institutions do this. Now they do this…again, the NDNQI has these two efforts. What is this unit level measurement? Then there’s a second component. The second component is called the RN Survey. And this is where as part of the NDNQI client institutions can elect to conduct this data collection activity. And where data is obtained directly from registered nurses who are involved in direct patient care. And the purpose is to look at evaluating RN job satisfaction in the nursing work environment. And these are used by VA facilities, the data from this to help them in their own quality improvement efforts. Again, it’s part of the benchmarking.   
  
So as these issues came up to ROD and we were asked as a national program office and our office is responsible here VHA in Washington D.C., we do the…we are the policy office for Human Subjects Research. And we are the ultimate group that determines whether or not if something is human subjects research or not, we have that authority. Which is given to us by VHA. Is looking at this…is it human subject to research or not? And I can tell you right now in terms of where I come from as a regulator that, I never want to make something research if it isn’t. So I come from that position and looking in evaluation when our offices are asked to evaluate this. And we just don’t make these arbitrary decisions that something is research or not. It has to meet regulatory criteria.   
  
And so in order to meet human such research, those definitions under the common rule which is the federal policy for the protection of human subjects which we as the Department of Veterans Affairs Veterans Health administration has signed on to as signed by the secretary of VA. It has to meet both definitions. It has to be researched and has to be research involving human subjects. And if either one of those are not yes, then the activity is not human subjects research. So what you see on your next slide is a definition under the common rule of what is research and what is human subjects. And again, I’m not going to, I’m going to be brief. But basically, research is again, a systematic investigation designed to develop or contribute to generalizable knowledge. That’s the key aspect of what makes something research.   
  
Because as many of you know here, you can have data that is indeed done as part of systematic investigations, but it’s not designed to develop or contribute to generalizable knowledge. Designed for internal purposes. For example is the, All Employee Survey. It’s deployed across the entire VA. We use those results…the agency [indiscernible] look internally at issues involving our employees and how to improve the organization. Now in terms of whether someone is a human subject under [indiscernible]. But in order to be human subject, someone the investigator…an investigator also means that their research team that they’re under, will obtain information from a human being through…or through the information about specimens through intervention or interaction or obtains and uses their data.   
  
Again, I’m going to read the definition, it’s right here. So that is when we first looked at this and said, if it is…this RN Survey a research study coming from the position that we don’t want to make it? But the answer is clearly yes. The NDNQI RN Survey is absolutely a human subject research activity. Press Ganey designed this RN Survey as a systematic investigation which is designed to develop generalizable knowledge by examining the relationship between the nursing work environments with nurse and patient outcomes. So while the client may use the data to improve their own internal process, it doesn’t change the fact that the data by virtue of the research activity is sent to Press Ganey who then uses this as part of this research activity to do the analysis. To again, develop generalizable knowledge by examining the relationships that they wish to examine. And that’s why they designed it the way they did. And the overall study with VA is Dr. Chris Morgan who is Vice President for Research and Measures in Science at Press Ganey itself.   
  
Now, the study is exempt human subjects study. And I’ll talk to you later how it could also be expedited. But really, in terms of the common rule, as exempt research study and it requires a limited IRB review. And the issue then is, okay, if it’s a research study, does it mean that the client institutions that agree to contract with Press Ganey, so that means that they are involved in the conduct of the research. Because just because the research study doesn’t mean that the facility itself or the client is engaged in the research, is involved in the conduct. For example, right now if I gave everyone on this a link, and I sent the link to a nursing research survey. Say, hi. My name is Karen Jeans. The Office of Research Developing was asked to send this survey it’s being…research survey that’s being done by X researcher at X. Here’s the link. Fill out if you want to.   
  
Okay. I am not involved, me as a person who works for VA central office. I’m not involved in the conduct of research. I am not part of the research study team. But if I start going into the gall and then start looking up individuals and trying to figure out whether or not they meet certain criteria, well, I’m going to send it to these individuals and I’m acting as an agent of the study. Then I am indeed involved in the conduct of human subjects research. If the institution or in this case the client institutions as we are common entity, then they need to find appropriate regulatory research approvals. So again, you can assume what is…what’s being done at the local level. Are these things which are required as part of the contract. As part of the protocol.   
  
Just because something is a protocol doesn’t mean it’s research by the way. Are they truly involved in the conduct of human subjects research? And again, indeed the answer is yes. Press Ganey has a very specific research protocol that site coordinators must follow if the client institution which is to enroll in the NDNQI RN Survey. And the protocol requires the site coordinator to recruit and participate in data collection for submission to Press Ganey. So if part of the requirement if the client institution says, I do want to do this part of it. That you will agree to follow the protocol as outlined by Press Ganey, which is indeed approved by the Advarra IRB. Which is a commercial…a for-profit commercial IRB. And all RNs that accompanied the NDNQI RN Survey are indeed research subjects.   
  
Now, Advarra IRB approved the research study. The Press Ganey RN Survey. And they connect this limited IRB review because it’s an exempt study. But their limited IRB review covers the conduct of the Press Ganey research team. The coverage of Dr. Morgan. It doesn’t cover any activities of the site coordinators that are involved in the conduct of Press Ganey RN Survey. So that’s…one of the reasons that we’re having this discussion today so that everyone is very clear what is involved, what it is, and what it isn’t. Because there’s been a lot of questions and because of the way you read the contract or read some of the communication, it seems like people can flip a coin. You can be either or. It is a research study. And I said it’s an exempt category two.   
  
And on this slide again, I’m not going to read the slide. But this is the regulatory criteria that is met in order for this study to be an exempt category two and why it is. So now we come to what really we want to talk about here and if you are a VA facility that is contracting with Press Ganey to conduct the NDNQI RN Survey and you want to do that component. It is a research study. That’s one thing to know if you’re here. Now it is exempt. But it requires a limited IRB review. And so what ORD and ONS have been doing is trying to figure out a way that we can coordinate the approaches to make it easier for VA facilities that want to participate in this. Again, we were brought into this about a month ago. And so we’ve been working on solutions.   
  
Now for sites that already conducted the activity or are in the middle of conducting it or you are planning to conduct it prior to September 1st of this year, you will use your own local IRB to do the limited IRB review. And it can be done using expedited procedures. It doesn’t have to be done by convened IRB to do a limited IRB review. It does require VA facility R&D committee approval. But again, as ORD policy allows, it can be done again during a designated review process. Again, it doesn’t have to wait for the meeting of the R&D committee. Now as a research study involving human subjects, it’s going to require privacy reviews and it’s going to require information system security review because there is data that is leading the system. And so those reviews will be done locally.   
  
But for the basic line of communications, ORD and ONS VA facilities, majority of VA facilities that are planning to conduct the NDNQI 2021 RN Survey will be doing it after September 1st, 2021. So for those sites, we have a different solution that we would…that we are offering, and we have coordinated in which the limited IRB review will be done by the VA Central IRB. Now the exception to that is if you’ve already started submitting to your IRB and they already done the limited IRB review are in their process. And you will have a choice. You either can…yeah, if it hasn’t been finished, you could withdraw the application and then then the VA Central IRB will do it or follow through with what you’re doing. But again, that’s your two options if you’re going to start this on or after September 1st.   
  
Now there’s no such thing as a centralized R&D committee at this time. So individual VA facilities have to indeed approved the study. But again, it can be done using designated review. What we are doing here is coordinating the central…the privacy reviews and the information system security officer reviews. The privacy reviews will be done by ORD’s privacy officer, which is Ms. Michelle Cristiano. And the information system security review will be done by the research support security division. And so that is the way we’re going to get it streamlined so that individual VA facilities don’t have to do that themselves. Now I do want to emphasize I’ve not talked about certain groups.   
  
Now there are VA facilities that we are aware of that do not have research programs. That indeed once you begin conducting the RN Survey or initiated the RN Survey, that requires research approvals. Please know that there is…it’s not a situation of oh, no. This is a bad thing because it wasn’t done as required. Because there’s a lot of confusion going on. But the problem is, you got to get it back into alignment. We are looking at solutions for VA facilities without research programs to figure out a way that we could maybe figure out a way to temporarily do something. Still it’s research. We have to get the research approvals in place. But that is why it’s very important if you’re a VA facility without a research program that you email Dr. Sullivan with the Office of Nursing Services (we will talk about Dr. Sullivan) and myself so that we can get an idea of how many research…how many VA facility without research programs are wishing to conduct the RN Survey of the NDNQI.   
  
Now for VA facilities with research programs, if you did this without research approvals, again, you have to get into alignment. So obtain the required research approvals. You do want to inform your research compliance officer. And again, please email Dr. Sullivan and myself. Now you keep hearing me talk about Dr. Sullivan, and Dr. Sheila Sullivan is the director of evidence-based practice and analytics within the Office of Nursing Services. And she is going to be the [indiscernible] lead PI for the NDNQI RN Survey that is being submitted to the VA Central IRB for conduct of the limited IRB review. And in order to use the VA Central IRB to conduct the limited IRB review, the VA facility must have a current IRB MOU to use the Central IRB. And the majority of our VA facilities without research…with research programs have that. In fact, I don’t know of any VA facility that doesn’t except the new programs that are coming up. So that’s that.   
  
In terms of the timing, which is always important, when are we planning to get this done? So again, Dr. Sullivan has been working with Press Ganey to get the materials which are required to submit the protocol for the limited IRB review to the Central IRB. And also for the R&D committee approval at the VA that she is using, or she has a WOC appointment. And we are looking at late August early September to have the VA Central IRB limited IRB review approval of the NDNQI RN Survey. Now part of that is going to depend upon getting some materials from Press Ganey that we’re waiting on. But right now, that’s what we’re looking at. And today is July 26th. So we’ve been working…Dr. Sullivan has been working for the last two weeks to get these materials submitted, so that if the plan. That’s our timeline we’re looking at.   
  
You will not be for those site to use the Central IRB, you know that normally when you submit a study to the Central IRB you have a local site application that’s submitted to Central IRB. That doesn’t happen with this type of study, an exempt study. So you won’t be submitting your local site applications for the Central IRB. However, you will need to submit your names to Dr. Sullivan along with the name of your VA facility principal investigator who is going to be conducting the NDNQI RN Survey at your facility. And what the beautiful thing is, is that all VA facilities right now who have research programs are on the solution…the enterprise solution called VAIRRS IRBNet. That allows us to communicate with each other.   
  
And so once the VA Central IRB makes its approval and it finishes it, Dr. Sullivan can make a copy of that approval to participating sites upon request by email. Or using VAIRRS, she can use the share function and share the package with your sites. Which again helps you submit to your R&D committee. So that’s how we’re going to utilize the Central IRB and using VAIRRS to facilitate this. Again, we’re doing a centralized privacy review. And that’s going to be done by Ms. Michelle Cristiano who works for. She’s ORD’s privacy officer. Now when Central Privacy reviews are done, each site does not submit a separate VA form 10250. Now, this study requires a HIPPA waiver. That will be done as part of the overall application that Dr. Sullivan is submitting as part of her package for the Central IRB’s limited IRB review.   
  
Finally, with the written HIPPA authorization, if there are site specific information issues that are needed, Ms. Cristiano will contact her site directly. And again, similar to what I just said how information will be conveyed. All these approvals that we’re talking about will be made available by email by request or by using the share function. We’ve also confirmed with the research support division that they will be doing the centralized information [indiscernible] security reviews for the NDNQI. Now with this, again, Dr. Sullivan as the Study Chair Lead PI is submitting a consolidated enterprise research data security plan. So each individual site again, will not submit their own ERDST to upload to the Central IRB.   
  
If there is site specific information that is needed, the resource support division will recheck to your local ISSO and your local PI, which is why we need the names. And so that is the plan for how to do the centralized information system security review. And again, these results will be made available again by emailing Dr. Sullivan. You can send it by mail or again sharing the packet with using the share function to VAIRRS. Now, there’s some other questions that are related not only to the research approvals, but also to other approvals. And I also want to state something here about the category, which I did not put slides. As part of the common rule and I don’t this to be an intense regulatory discussion, but for those sites that are already participating in the RN Survey and we are aware that a number of IRBs had already reviewed the study.   
  
Now this study could be done either as exempt study or as an expedited study. One is exempt, one is not exempt. If your IRB treated this as an expedited…I mean, as a nonexempt human subject study, and it can be expedited as a category seven. That’s okay. Don’t go back and change it. You don’t need to convert to an exempt study. And so I want to emphasize that that is okay. It just means that when it comes…if there’s any amendments or modifications that are needed for that study, those will be reviewed by the IRB since it has continuing oversight. As an exempt study, the R&D committee reviews the modifications amendments unless it impacts the limited IRB review.   
  
There’s no continuing IRB required for exempt studies. And as expedited studies, this study would also be eligible for…this will not have continued review unless mandated by the IRB. Lots of questions have been asked whether or not this study requires OMB clearance. It is subject to the Paperwork Reduction Act? The answer is no. The subjects are federal employees. They’re not patients. And so, as a federal employee, survey selections and information involving that are not subject to the PRA. So you do not need to get…you do not need to go to the PRA office and ask for determination because it’s not applicable.   
  
Now I said at the very beginning that there’s no national contract. But in terms of VA when we’re doing surveys, a lot of times there’s certain criteria if it’s being done at multiple sites and it’s called, OAC Review Approval. Organizational Assessment Committee Review Approval. The office of Nursing Service has already been communicating with the OAC to determine whether or not it will be needed for the studies since we’re trying to coordinate this across multiple VA facilities. Even if needed, ONS will take care of that. Your local facility does not to do that. So we wanted to point that out as well. In terms of contracts, there is again no national contract that exists right now for VA facilities who choose to participate in the NCQA…excuse me. The NDNQI or the elective component…the other collections component called the RN Survey.   
  
Now in the future that might happen, and again, it’s not…ORD is not going to get into contract issues. And that’s something that is a result of this. We’re all looking these…how can we do an enterprise solution so that again, we coordinate so everyone doesn’t have to negotiate separate contract language. And key issues with the contract can be addressed. So information about more about the contracts. That will be given to you as that is made available in terms of what to look at and things like that. But again. right now these are individual contracts that are executed by VA facilities.   
  
In terms of union reviews, we received a number of questions about that as well both within the Office of Research and Development and also within the Office of Nursing Services. Again, this is where the Office of Nursing Services is working directly on whether or not this does indeed require national union notification, national union approval. So again, what we’re saying here is that your local sites do not need to work on that component. The Office of Nursing Service is coordinating working on that component and then more information will be available as we get clarification. But again, that’s not something each of your individual VA facilities have to do is go through your local unions to make determinations on what is needed.   
  
Now we really truly…one of the reasons that we put this on the slide here is that we’re trying again to make sure that VA facilities that are conducting the NDNQI and indeed want to do the NDNQI RN Survey that with your knowledge about those sites so that we can assist, answer questions, and again coordinate on issues so that each of you separately are not having to answer the same questions. And so what we are asking you to do if you are a VA facility that if doing this is to please contact by email, send an email to Dr. Sheila Sullivan and send an email to me. So that we can coordinate on different types of issues that separately, our groups will have. And so that is something again I want to reinforce over and over again. And again, we wanted to leave plenty of time for questions.   
  
I cannot again, emphasize enough how important that we feel your central office that the NDNQI is and as well as the RN Survey. These are important. They are important to the agency which is why we are working together to get this information out to you to coordinate. We want to make this as seamless as possible and also make sure consistent information is coming down. We are asking as we are working with Press Ganey, if you have a question about the study, the RN Survey study that you direct questions to Dr. Sullivan instead of emailing Press Ganey separately. And that is for several reasons. Number one. She is going to be the study chair lead PI for the central IRB, limited IRB review application. But also, it’s so that if there’s multiple questions coming down, we can update the guidance as we need it.   
  
Right before this phone call on this webinar, we are issuing a guidance document which contains much of the information and a little bit more actually than what we’re covering in this webinar as part of a guidance document. ORD will be posting that guidance document on our policy guidance website. ONS will disseminate it as per ONS procedures. But we can update that guidance based upon the type of questions we’re receiving from you with VA facilities. So that’s why again we want to be able to do that. Again, additional information and updated will be sent to you as it becomes available. And again, we want to…okay, we can’t say it enough, please let us know if your facility is planning or have been participating in the 2021 NDNQI RN Survey.   
  
So with that said, that is the end of his part of the webinar. We will indeed…we have recorded this webinar. We will be recording the next part of this which is the question/answer sessions. Approximately a week after this webinar after today, the webinar is posted on ORD’s webinar site. We will also send that link to the Office of Nursing Services. The slide set will be on there as well as the handout. So with that said, we are now ready to start the question-and-answer phase of this. And we will go with that. So I’m going to ask my panelist to also participate in this portion. And I think Kate, we are ready to get started.

Kate: Alright, excellent. Thank you to everyone who has already submitted a question. And just a reminder that if you would still like to submit a question, you can do so using the Q&A box.

Dr. Karen Jeans: Okay, so the first question and I’m really glad for this first question. So if IRB…the question is, so if IRB says it’s not a human subjects research activity, we’re good to go? The answer is no. If your VA facility is conducting the RN Survey, it is a human subjects research study. That is what it is. And so that’s one of reasons we’re conducting this webinar today. There is no question it’s research study. And in your individual contracts you’ll see that, and you’ll see it in the RN Survey, the protocol itself. And we understand the confusion because sites were using this data for their own purposes. So you’re using it internally, but it doesn’t change the fact that the data is going to Press Ganey and they are indeed using that to conduct a research study.   
  
The site coordinators, if you are indeed doing what is required by the protocol, by the site coordinator protocol, the site coordinators protocol, the site coordinators are clearly engaged in the conduct of this human subjects research activity. So it is indeed a human subjects research activity and you will need to obtain the required research approvals. Thank you. Okay, and can we blow that up a little bit bigger? The next question is, what are the minimum requirements to be the PI? Okay, so this is a great question. Number one. To be a principal investigator in VA, first of all you have to be at a VA…you have to have a VA facility that has a research program that has been approved by the Office of Research and Development and the Office of Research Oversight.   
  
In order to be a VA investigator in VA, you cannot be a contractor. So you can have a walk, you could have an IPA, you can have a paid employment. But you cannot be a contractor. And if there’s…and so that’s…and of course qualified to conduct the site. But that’s the minimum requirements to be VA PI. The big one being that you have to be at a facility with a research program and you have to have a VA employee status. You cannot be a contractor. Okay, the next question. Okay, can you show me the question? I’m seeing a lot of slides.   
  
Okay, so the next question is, what is the turnaround time for the centralized approvals?

Kate: So sorry. I didn’t realize it as sharing that screen. Here’s the next question.

Dr. Karen Jeans: Okay. Alright. Okay, so the next question is, when do you anticipate having the central IRB privacy information security approval documents available so that local facilities can submit for local R&D approval? Thanks. The right question. We project that by the end of October early September, we will have those approvals. That includes the limited IRB approval and the reviews which are completed by the privacy officer and the information system security office reviews by the resource support division. That is all dependent upon getting the material that we’re still trying to get from Press Ganey. But that is the plan and that’s before we had this webinar, this is why this has been calculated in terms of, what is the rejection. So that is what the timeline we’re working at so that you yourself can plan on your next steps. Thank you.   
  
And what is the turnaround time for the central approvals? I think I…we just answered that question, so let’s move to the next question please. And I answered that question too. What is the minimum requirements to be the PI? That’s again, minimum is you have to have a VA, so okay? Question a little off topic. Does approval by IRB also apply to the Pathways to Excellence Nurse Survey? So I’m going to ask Dr. Sullivan to help me here, because I actually do not know what the Pathway to Excellence Nurse Survey is. I don’t know. I have no knowledge of that.

Dr. Sullivan: I’ve got that Karen. Thank you so much. So if I’m interpreting the question correctly, you’re referencing the Pathway to Excellence Nurse Survey that is administered as the final step prior to designation. This particular survey does not contribute to generalizable knowledge because it is looking at a cross-section response of your agency and that information is not engaged in any sort of data collection that contributes to how other people are measured. It does not contribute to a benchmark, which is what does happen in the NDNQI Survey. So that’s the key distinction there. So you will not require IRB approval for the PTE nurse survey.

Dr. Karen Jeans: Thank you Dr. Sullivan. The question…okay, we’ve been doing the NDNQI RN Survey since 2008 and got original approval from IRB at that time. And that’s great and wonderful. But this requires its own approval. And that’s absolutely outstanding. And so you will need to approve the 2021 RN Survey. So fantastic. Oh, that’s very nice. Many thanks to Dr. Jeans and I would say Dr. Sullivan for the support in assuring we are compliant in connecting the NDNQI RN Survey for our RN staff. You know, we’re all in this together. We rise and fall together. And I think that’s one of things that if we don’t realize that, we…I think that’s why I love working for the VA. And I’m an IT nurse by the way. So this is important.   
  
So again, that’s why we want you to tell us if you are participating so again, we can roll out questions that if one site has the question, I guarantee you everybody else does. So that’s why want to update the guidance with your questions. So thank you, and we appreciate your working with us. So thank you. Do we have to resubmit a request for IRB approval every time our facility does the RN Survey? If so, why? Excellent question. Because it’s a different protocol. The protocol that is permitted for NDNQI 2021 RN Survey applies only to the 2021 RN Survey. The data collection measures, the instructions that are given to research subjects, the data collection itself. And so it’s not a longitudinal study. It is its own separate protocol. So that is why. Otherwise, we wouldn’t…you wouldn’t have to have a separate approval because indeed, it would be just one protocol. It is a separate unique study. Thank you.   
  
We are slated to hold survey in October. Would you advise us to go local, then share with national. So that’s a question. And I’m glad again Dr. Sullivan is here with me because it depends. Number one is, we are hoping that we will get the…our plan is to have a Central IRB, Limited IRB Review done by the end of August, early September. Again, the R&D committee approvals can be done by a designated review. Doesn’t mean its convened. So you would easily have that if we’re on target by September one. I guess first my question is, have you started submissions? If all goes right, there should not be a need for you to go local because there’s still plenty of time. And that’s why again why we’re doing this seminar today…webinar today. But I’d like to also ask Dr. Sullivan for her opinion.

Dr. Sullivan: I think that…thank you Dr. Jeans. I think that the question again a very excellent one and it also depends as Dr. Jeans said, where you are in the process of your application. I am very optimistic that I would be able to turn this entire package in by midweek. Very optimistic that that will happen. However, I don’t know exactly how the turnaround will go. I’m waiting on some people to give me signatures. So CIRB has always been excellent with rapid turnaround. But then the next piece of that come in how quickly will your R&D turn it around for you and will you still have time to do all the activities that are outlined in the protocol to meet your deadline. So the answer is, I can’t tell you exactly what will happen. I do have some believe that we have sufficient time to allow you to go with the national submission.

Dr. Karen Jeans: Okay the next question is, VISN 12 has a contract with Press Ganey for both patient and NDNQI surveys. We already have AFGE approval already. Okay. Thank you. And that’s information that we will…that’s why we want to do this. Again, both of our national office are here. That’s information we need to know. We thank you for conveying that information to us. Thank you.

Dr. Sullivan: So Karen, quick point of order there. The NDNQI database where you’re turning in your patient outcomes, that is nor research. That is not our concern. It’s the RN Satisfaction Survey that is different and separate in its research. So if that’s what you’re doing in VISN 12, certainly that’s wonderful. But we do require…it is research, so we would require that you take that back through the IRB. So I hope that makes sense. So if you’re just doing the outcomes, that doesn’t require the IRB review at all. It’s the RN Satisfaction Survey.

Dr. Karen Jeans: And I’m going to also…again, we try very hard to do the acronyms, but I’m going to be honest, I do not know for my…what AFGE?

Dr. Sullivan: The American Federation of Government Employees.

Dr. Karen Jeans: Okay, thank you. Okay. Thank you. How may VA participate in NDNQI in general and in the RN Survey specifically? Is there a potential for a national contract?

Dr. Sullivan: I’ll take that one Karen.

Dr. Karen Jeans: Thank you.

Dr. Sullivan: One of the things we’re trying to collect from this is how many people are doing that. Because since each contract is done at the local facility, VA national office genuinely does not know how many people are doing it. So how you can do that is through a contract that your agency would create with Press Ganey and you would select what portions of that contract you would employ. The NDNQI and the the RN Survey. There are also additional magnet questions as an option to the survey that can be selected. But again, that depends on your local contract. As for a national contract, right now our best guess is that we have fewer than 20 agencies who are using the survey. So at this point in time, I don’t think we can create a compelling case for those outcomes since we have so many of our own outcomes. I think if this continues to grow, that case can become strengthened and would certainly be something that we can discuss in the future. Great question. Thank you.

Dr. Karen Jeans: What about educational level. I’m unclear what is the question. So I’m going to ask for the sender of that to please send us…give us some additional information on the question so that we can address it. Thank you. You say that continuing review is likely not needed. But what we need to obtain IRB approval every year as the survey is often administered annually. The continuing review is different than IRB approval in terms of a new protocol. This protocol…you’re right. There’s two reasons why you’re not going to need continuing review. If this study only last one year, then number one. It’s not going to be required to get continuing review for two reasons. If it exempts, there’s no requirement for an R&D exempt study to go through continuing review by an R&D committee.   
  
If it’s under the IRB, again, it would be under XI category seven if it’s not exempt. Again, under the common rule, continuing review does not occur for any nonexempt study that’s expeditable unless the IRB specifically requires it. But in terms of, you will need to obtain IRB approval every year as the survey is often administered annually. That’s going to depend upon NDNQI. I mean, Press Ganey. If they continue…if they design the 2022 RN Survey as again a research study, then the answer is yes. That would be a new study. And so it would need the require research approvals. So that’s how that would come into play. It all depends upon what Press Ganey decided to do in terms of how it structures its deployment and this case its design and how it uses the RN Survey. So that’s the issue involved here. Thank you.   
  
So what is the minimum educational level for the PI? I’m going to start and I’m going to go defer to Dr. Sullivan as well. In terms of the Office of Research and Development, we don’t set a…we don’t say you have to have…for example. Dr. Sullivan and I are both PhDs. Does that mean you have to be a PhD to be a PI? No. It means you have to be qualified to conduct the research. So we in the Office of Research and Development do not place a requirement in terms of, you must have x educational level. Because that’s not what’s required by the common rule. Are you qualified to conduct the research? Do you have the qualifications as determined by the institution to be able to conduct the research? So ORD does not have a minimum educational requirement because the federal regulations themselves don’t get into that that you have a certain degree or a certification. And I’m going to defer to Dr. Sullivan as well.

Dr. Sullivan: And I think…Karen correct me if I’m incorrect. But I think that’s part of the role of each individual R&D is to review the PI application. Because I mean, I can’t make that determination in this office. I mean, I wouldn’t know so many of people who would apply. So that’s the responsibility and why the local R&D is asked to review each of these studies. So I certainly would encourage you to select someone as your site coordinator who has the ability and hopefully some background in conducting research of this nature. Because that way, the R&D would be more comfortable in approving them.

Dr. Karen Jeans: And my last statement, I’m clarifying this is also, you cannot be a student. So you cannot be a student and be a PI. And say, oh, great. For you to be the student, it’s a great learning activity for you.

Dr. Sullivan: This cannot be [indiscernible] your capstone.

Dr. Karen Jeans: Right. That exactly right. So we want to…because it would be very tempting. And I have someone who’s a faculty member I could see that coming. So I’m really glad again that someone asked this question. Thank you. Is there any action necessary from our organization related to past surveys conducted? Recent change to site coordinator and unsure if previous coordinator went through the limited IRB process or not. From ORD’s position, we are dealing with the 2021. So that’s the information that we’re dealing with. So I can’t address what happened with ‘20 or ‘19 whether or not that was a research activity or not. Or how Press Ganey designed it. And so that is a separate issue. And so we’re not addressing that right now. I don’t know. That’s something we will need to follow up with Press Ganey about. But right now, there’s no action that we’re going to tell you to take right now in relation to previous iterations of the RN Survey. Because that’s not the information we have available to us right now. And then I’ll defer to Dr. Sullivan.

Dr. Sullivan: No, I concur with what you said Karen. I have no addition.

Dr. Karen Jeans: Is national concurrence for union being obtained or is local union required? Thanks so much. Great question. Again, I want to get applaud to Office of Nursing Services here because when again this issue was brought to us by VA facilities, they are coordinating to do a national notification. And if necessary, get those approvals at the national level, so again, your local unions. You don’t have to seek that at your local level for those who’ve not already done it. And again, we’re trying to consolidate the effort that’s required. So for right now for what we’re telling you to do, if you haven’t already done it is, don’t do that because it is being addressed at the national level. If that information changes, we would convey that to you. But that is what is currently in process. So you do not need to go through your local union notifications approvals at this time. Thank you.   
  
Will this include inpatient and outpatient research study nurses? We will need…again, the protocol describes the specific criteria that is required. That can be a separate conversation in terms of what the criteria are involved in how the Press Ganey, and the protocol defined direct patient care RNs. So again, it would depend. We are talking about research study nurses. Are they involved in direct patient care or not? So it depends. So we’re going to have to…to answer that question, we would have to go through the protocol and ask a separate question. So we can again put this in guidance as we look at this. But thank you for the question. But I can’t answer that without reviewing the protocol. So I will defer at this time.   
  
When you have an algorithm or a checklist to ensure we follow the process explained. We actually have a…we included a guidance document that is…that has been included as part of today’s handouts. We could probably make a checklist out of that. But the steps are there what’s required and so is explained. And in terms of providing guidance that we do required to go through IRB as I see this as categorize as a QI, you do not need a memo. Because that guidance document has been issued by the Office of Research and Development in conjunction with ONS. That is the formal notification that this has indeed been determined to be a human subject research study. The RN Survey. Not the NDNQI.   
  
So that guidance document which clearly conveys determination is indeed there to give to your facility. And again, the limited IRB review is again, that is exempt studies. Again, if you want to make it expeditable, make it go through IRB oversight and not exempt that’s your choice. We do not recommend that. Again, the whole purpose of the revised common rule was to decrease the burden on the IRB. This is like minimal risk activity and so that’s why it is an exempt study. And again, as part of the categorization, we are putting it through a limited IRB review to meet that regulatory criteria. Thank you. We will get local approvals. Is there anything we need to do to close the loop with ONS after completion of the survey? I’ll defer to Dr. Sullivan.

Dr. Sullivan: Thank you. The only thing…we’re certainly not looking to collect your data. That is not the objective of this central work. We’re just trying to lighten your load in going through this regulatory process. It would be helpful for us to know that you have participated in that particular survey just by emailing me at the address given earlier just so that Dr. Jeans and I know this is somebody who’s participated, and we can ensure that there’s compliance. But again, we are not seeking out your data. That is so not the point of this. But thank you for the question.

Dr. Karen Jeans: May I contact you to verify that anyone outside the TVAMC R&D service line has asked to participate because none of the PIs have stated they are participating? You can contact myself or Dr. Sullivan absolutely.

If we pursue the local option due to timing, who is responsible for ensuring privacy and IT concerns? Again, the RN Survey is a research study. By policy, these studies are required to have privacy reviews and information system security reviews. So that will be done locally. Now here is…if you do pursue the local option…again, those privacy and information security reviews are going to be available once they’re done. But they won’t be done until the Central IRB limited IRB review approval is done. So that will have to be done locally. Thank you. Okay, we’ve already answered this question. So thank you. Is the NDNQI an annual survey and will approve be required each year or how often is conducted? Again, I want to reiterate what Dr. Sullivan is saying. There’s the NDNQI and then there’s the NDNQI RN Survey. They are two different things. And so what most sites…what sites do is they do the NDNQI and then there is an elective component that you can also do, which is the RN Survey. So if we’re talking about the NDNQI, that is not research. So research regulatory approvals are not reqired. Again, going back to the next year, we don’t know how Press Ganey is going to design the 2022 RN Survey. So we can’t answer what will happen in 2022. But my thing is, let’s get through 2021.

Kate: Alright. And this will have to be our last question.

Dr. Karen Jeans: ONS is submitting a memo to VHA labor-management relations to notify labor partners at the national level, the local notifications are not required. RN staff who participate in the survey serve as informed consent to participate. Yeah, it is for an exempt study, yes. And yeah, again these are subjects. And I think this is probably submitted by ONS. And I thank you for this comment. If it’s an exempt study, again, ORD policy requires a permission. And terms of if it’s done under the expedited approval under the categories of a nonexempt study, it’s called a Waiver of Documentation of Informed Consent where again, you don’t do a written consent, but the IRB has to review the Waiver of Documentation Informed Consent.   
  
And then the subjects are given that information and then the completion of the survey is basically how you confirm that they indeed decided to choose to participate in the study. So that is how it is done. Again, we are saying this because the categories are not mutually exclusive, we do recommend that the study be approved as an exempt study with using limited IRB review and not as a nonexempt study. Other expedited category seven. Okay. So I’m going to…before Kate closes it up, I want to say first of all, thank you so much for being in this webinar and allowing us to discuss this today. And I’d also like to defer to Dr. Sullivan to see if she’d like any statements to make.

Dr. Sullivan: First of all, thank you Dr. Jeans for your collaborative behaviorally and how kindly you have assisted us through this process. And I want to thank everybody nationally for joining into the call of learning about this situation. Please don’t hesitate to reach out to either myself or to Dr. Jeans with any additional questions and we will respond as soon as we can. We certainly encourage you to engage in these activities. We just want to ensure that we have followed the regulations to ensure that we protect human subjects. So thank you so much.

Dr. Karen Jeans: Thank you Dr. Sullivan. And Kate, I think we’re ready to close out.

Kate: Alright. Thank you again everyone. We hope everyone has a great day.