Kate: Good afternoon, everyone. Please just give us one moment to share our screen.

And, Karen, we can see your screen, but you still have—there we go, perfect. Thank you.

Alright, good afternoon, everyone. Hello, and welcome to today’s ORPP&E webinar titled Proactive Calling of Veterans for Phone Recruitment. 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 being presented in lecture-only mode; therefore, the audience is muted. This presentation is being recorded. Handouts were sent out in advance to everyone that registered. For those that did not receive the handouts, you can access them through the SharePoint link that is in the Q&A box. I’m going to pause for one moment here to give everyone a moment to locate the Q&A box on the right-hand side of your screen. Questions will be addressed during the question and answer portion of the webinar.

When submitting questions, please send to all panelists. Please do not use the chat feature to submit questions. Webex Events does not automatically enable you to see comments submitted by others; however, we will share all submitted questions with the entire audience by typing the phrase, thank you for your question to each question submitted. You can make the Q&A box larger by undocking it, and then clicking on the corner of the box and dragging it to resize. This is done by double-clicking on the middle of your WebEx Events screen to undock the Q&A box and then resize it. To return to the normal view, simply double-click on the middle of your WebEx Events screen.

Once you exit the webinar, a quick survey will pop up in the browser. We would appreciate your feedback regarding today’s presentation to improve future webinars. If you have difficulties running the 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 by using the call-in number that’s provided on the slide and in the registration confirmation email. And with that, I’ll pass it along to Dr. Karen Jeans.

 Dr. Karen Jeans: So hi, everybody. Thank you, Kate. My name is Karen Jeans. I’m the Director of Regulatory Affairs here in the Office of Research Protection Policy and Education here in ORD, and I’m going to be your presenter this afternoon. Dr. Klote has been called away, so we will be discussing this really exciting topic for the next hour. So I’m going to jump right in and get us going. Again, the title is Proactive Calling of VA Subjects of Research Recruitment, and we’re going to define what is meant by proactive calling in relation to what has been a memorandum that you’ll be hearing about this afternoon.

We have five objectives for today’s webinar. Number one, we’re going to, again, define what is the term. This webinar is designed to bring to all of you in the research community the introduction of the limited use of proactive calling for recruiting VA subjects in VA research, so we’re going to be discussing that and also reviewing what are some acceptable needs to contact subjects when you’re not using proactive calling. But the breadth of this entire webinar is about the process that’s going to be used by ORD in terms what are the types of studies, what is the process that can be used, how is it done, and specifically what are the criteria for those studies that can come to ORD to request and application for proactive calling, the recruitment of VA study subjects. We’re also going to discuss what the evaluation process looks like, and again what’s the documentation you’ll get back.

So we’re going to spend a little time here, and again I want to have enough time at the end of the seminar for questions. We’re going to discuss what—again, briefly review for the purposes of this presentation what is research recruitment. Again, recruitment is not referral. Recruitment is when you’re identifying eligible subjects. It’s active. You are explaining the study to the potential subject as agents of the study, obtaining informed consent, and it also includes retaining those subjects until they complete. Whether it be they withdraw or whether they complete the study.

Recruitment materials can take many different types of examples. Now today we’re going to be talking only about non-exempt studies. And I want to reinforce that any type of recruitment material must be approved by an institutional review board, but recruitment materials can indeed—you’re your traditional fliers, information sheets but also electronic types of mechanisms that are used.

But for purpose of today, proactive calling. Proactive calling is contacting a potential VA subject by telephone for the purpose of that initial research encounter without prior contact by letter; by email; or through in-person, as in a clinical encounter regarding the study. And that’s how that term is going to be used today. It’s traditionally called cold calling.

So before we jump into this, again, we need everyone to be on the same page. Now our current policy, which remains in effect, by the way, is in VHA Directive 1200.05, Paragraph 5(g), and section 8 states: “During the recruitment process, an investigator is responsible for making initial contact with potential subjects in person or by letter, and a letter can be hardcopy or electronic, prior to initiating any telephone contact, unless there is some type of written documentation that the subject is willing to be contacted by telephone about the study in question or specific kind of research as outlined in the study.” In other words, this is saying you can’t cold call people.

And we also have as part of this notes within that directive which is a policy requirement that in terms of how you can contact, when you do a telephone, what you have to do. You have to provide a telephone number. If the contactor sends the letter prior to the telephone contact, the VA investigator must sign the letter. But also, that’s part of the policy requirement in terms of how this operates with our current existing policy.

And a lot of people have asked, well, why did ORD even set this in place? Why is this even a big deal? And the reason goes back—and many of us have been here a long time. It goes back to 2006 when a VA laptop, portable computer, and an external hard drive containing personal data, including Social Security Numbers on a reported 26.5 million Veterans and active duty military personnel were stolen from the home a VA employee. And there was a lot of repercussions from this. It caused basically—there was delay in the time that the appropriate people were made aware, and there was great concern about the potential for fraudster to contact veterans and present themselves as, hey, by the way, your data may have been stolen—because this was on CNN, it was on all the newspapers, because it was a big deal, this was not a trivial event—to scam people.

And as a personal aside, my father, who was a veteran, he was one of the people who actually got a call from a fraudster during this time period and was asked, oh, have you heard about the data breach that occurred with VA? We have your Social Security Number as blah, blah, blah, and of course it was wrong. And so they wanted him to give the correct Social Security Number because they represented themselves as the Department of Veterans Affairs.

And so as a result of this and the great concern that was happening is the Principal Deputy Under Secretary of Health and CRADO, ORD’s Chief Research and Development Officer, issued a memorandum which, again, memorandums have the strength of policy. And memorandum informed the VHA research community that as of that moment, which was July 10, 2006, that you cannot do cold calling, that if a VA researcher wants to contact a veteran—and it was specific to veterans—for study recruitment, that you had to make some type of initial contact first. And so we mimic that memorandum by putting it in policy within VHA 1200.05, and now the current VHA Directive 1200.05 because it just doesn’t apply to veterans, it applied to any VA subject. Because as many of us know on this call, we not only recruit veterans as VA subjects, we also recruit other populations, including employees, including caregivers. We have a diverse subject population that are involved in the type of VA studies that our agency conducts.

Now again just as a brief review, what I’ve included on this slide—and I’m not going to read through—its examples of different methods to contact VA subjects for recruitment. We could literally spend the entire hour going in depth in terms of the different issues involved, different types of advertisement within medical centers and also in terms of advertisements. So what I really want to get to is the fact that—why we’re here today.

Now historically as we are a VHA, Veterans Health Administration, the traditional, usual means of recruitment when you think about research studies, especially when you’re talking about clinical research—and we’re not talking about HSR&D research, which is critical by the way—but many of us do clinical trials. Well you think, okay, by the way, we’re going to put a flier up. Okay, that's one way to do it. We have someone who is seeing the patient who would be a subject as part of a clinical care encounter. And also, it’s not uncommon to set up booths, and this is something we see a lot with HSR&D type studies or social sciences studies, survey studies, interview studies where you set up a table or set up some type of—in a cafeteria. In the lobby, of course with the facility’s permission and say, hey, we have a focus group we want to do as part of the research study. You set up an event table where you can recruit, again, the individuals who are coming to the facility, and you’re targeting usually, of course, veterans for VHA. And these are the traditional methods that have been used for many of our studies.

But as we all know, the rules have changed. And the COVID pandemic has indeed changed our entire way of thinking, entire way of how we’re doing things. And we saw immediately a slowdown in recruitment because even our clinical care, our clinical studies because the traditional methods no longer existed. People were not in the hospitals. Even employees. We’re not in the hospital unless you were essential personnel. Now even the way we did consent has changed, moving toward an emphasis of not using paper, of course the iMedConsent. Digitalizing your paper consents. And of course DocuSign. And so we’ve tried to deal with this in different ways, and again trying to recruit subjects through letters to subjects, telehealth appointments, and again the Volunteer Registry that are established for research purposes.

But there’s where we are today. One of the big issues that have come out as a result of the COVID pandemic, which continues and is active—and again, I’m here in Arkansas today, and it’s an incredible situation. This is hopefully a once-in-a-lifetime experience for all of us on this phone call today. But the pandemic has truly changed everything we’re doing. And as we have done some evaluations and looked at the type of clinical studies that are indeed being done in the VHA, that are being done by the country in terms of we’re, again, doing research to improve the life of veterans. That’s what we’re here for. There are, indeed, certain situations where the ability to proactivity call VA subjects for study recruitment is indeed appropriate. We have evaluated this within the Office of Research and Development. We have spoken with other groups including legal, the Office of Research Oversight, and of course the under secretary’s office.

And part of the reason—it’s like we just didn’t flip a hat and say, okay, today let’s look at this and say we can do some cold calling now. No. It’s proactive calling because what’s happening and we’re seeing as a result of the pandemic is that there’s sometimes some studies in which a letter or an email or that clinical encounter to say, hey, we’re going to call you before we get you into the study to see if you want to be in it. It can occur because of the timeframe. We also see that if you put adequate measures in place to protect subjects’ privacy, because that’s a big deal, and the ethical rights to someone, just because you’re a veteran—at let’s target veterans of course—doesn’t mean that you get to get solicited all the time. That’s not what it means to be—think of yourself.

When any of you have been hospitalized or are in a doctor’s office, that’s not a card to say you can call me for whenever you want to for whatever you want to do. So that’s a big deal also, protecting not only your privacy but your ethical rights for why you originally entered a healthcare institution. But also some of these studies, their potential impact on lifesaving therapies warrant that type of event, of being able to do a proactive call. And again, all this is coming around as a result of the pandemic.

So as a result of this—and we have spent several months discussing this. This is not something, again, that just happened today. ORD, again, after concurrence of other national program offices, went to the under secretary, the Acting Under Secretary of Health, which was Dr. Stone, and Dr. Stone signed a policy, a memorandum into place. And that policy memorandum, which will be posted on ORD’s website by tomorrow, dated June 29, 2021, allows for the proactive calling of VA subjects for recruitment in VA research but only within the parameters that ORD establishes with a formal ORD approval process.

This memorandum rescinds that earlier memorandum, which was issued on July 10, 2006, which was again signed by the PDUSH and the CRADO, so that memorandum is no longer in effect. However, this memorandum clearly reinforces this does not mean it’s a free-for-all, that it’s okay, the policy is rescinded so, therefore, we can cold call. No, that’s not what it is. The memorandum is rescinded. So what I want to reinforce here is that the policy requirement in 1200.05, which does not permit cold calling, remains in effect, except for the studies that we’re going to discuss here in just a few minutes in which ORD formally approves the use of cold calling. Part of the requirements of the memorandum is that ORD establish exactly what we’re talking about today.

Now many of you are asking, well, Karen, you just said that 1200.05 policy is not rescinded. That is true. What will happen is similar to what happened in 2006, is that 1200.05 will have a technical amendment. It takes several months to get through a technical amendment. And so during that time period until we can update the policy to reflect what is not in the current memorandum of June 29, 2021, the Office of Research Oversight will exercise discretionary enforcement of the cold calling policy based upon the processes that you’re hearing about today, which includes the ORD approval of proactive calling for a specific study.

So as we go into discussing the process that ORD is using. One asked, okay, 2006 has happened because of the data breach. Is it truly safer to call VA subjects now? So when you look at the data and you look at we’re 15 years from that event that happened, we have seen a dramatic increase in unsolicited telephone calls. Thinking about each of you on the call right now how many times you get a call. And based on some data, some people say that 50% of all calls on your phone calls, your cellphone, your landlines, are unsolicited. It’s unreal, again, as a personal aside, how many I myself get on my VA phone here in the office in D.C. And what we’ve seen in a radical increase in sophistication. Why is it increasing? Because it’s successful. When something works, people try it more.

However, we’ve also seen an increase in sophistications of the methods to stop the solicitations, more active involvement by different groups to stop these. And also even by our own carriers. Our cellphone comes where many time where you’re getting an unsolicited phone call, you will see when it shows up on your phone potential scam or potential spam, different words to clue you in that, hmm, this is probably an unsolicited call that you don’t want to answer. So we’ve seen that because technology is working to try to deal with this, and so that’s something that we didn’t see back in 2006. And part of this process that ORD is using, we are putting measures in place to protect, again, the privacy of subjects and make sure that the are ethical protections for those studies that are approved for proactive calling for recruitment.

And again, we’ve seen a dramatic rise in telehealth as a result of—as we’re seeing this from 2006 to 2021. We do want to emphasize that telephone encounters by clinical providers even without video are also considered a form of telehealth.

And again, before we jump in—because this is important because one of the things we’ll be talking about is using alternative methods—we have, of course, a rise in the use of email communications. Now MyHealtheVet is used to communicate with veterans as part of clinical care. It can be used to communicate with veterans as part of the VA research studies, but it cannot be used for recruitment. MyHealtheVet comes from the Office of Connected Care, and that is not permitted because the veterans do not have the ability to opt out or opt in of saying I want to receive research solicitation. So until that mechanism is put in, that is why MyHealtheVet does not permit that type of recruitment to occur.

We have some guidance documents. We have some draft guidance documents. Again, this is a separate call that we can discuss the whole time about email communications. I’ve included here on this slide about use of email to communicate and when you can use it to recruit. Again, I want to emphasize, of course, anytime that you’re communicating with a VA subject, you cannot use your personal email accounts.

But I really want to jump in right now in terms of how does proactive calling work. So as you’re listening here before you even think about doing this, I wanted to emphasize that the number of studies that are expected to obtain ORD approval for proactive calling for subject recruitment will be small. It is not going to be similar to DocuSign where basically almost all of those—many of those studies do indeed receive approval. So the criteria are much stricter than what is involved with DocuSign, so don’t compare the two. Also to reinforce if a veteran—or VA subject, excuse me, has documented his or her permission for research contact, for example there’s a study in which they say, okay, I give me permission to be contacted by phone about future studies, you do not need to go through this process because the subject has already documented his or her permission to be contacted for future studies. Again, you can only contact that subject according to what is in the consent and the HIPAA authorization.

We also want to reinforce that in terms of in-person, if the initial contact is done during a clinical telehealth video or clinical telephone encounter, that is now just an in-person. So again, as you’re thinking, do I need to apply for proactive, we wanted to reinforce that because we went you to evaluate whether other methods of subject recruitment can be utilized before you go in with an application.

In terms of the actual process of proactive calling for subject recruitment, the request process, we will be using a designated ORD SharePoint site. We are recommending strongly that you obtain ORD approval prior to IRB submission. And that is because if you go in, say, to your IRB, and you’re going to say, I’m going to use proactive calling. Okay, then we come back as ORD and disapprove it, you’ve got to go right back to the IRB. So that is the rationale for seeking approval prior to IRB approval.

There will be no blanket approvals. And why that? I mean, like let’s say you have an investigator that’s doing a whole group of studies, and you’re saying, okay, I want this group of studies that I’m doing to have proactive calling. They will be specific to the individual study. However, you can also request proactive calling for individual subjects within a study, so it’s not an all or none approach. However, again, reinforce it. The IRB must approve any subject recruitment method.

What we’re going to do is now review the ORD criteria to apply for proactive call approval. There are nine criteria. First is that the research must a nonexempt study. Exempt studies are not eligible for this. The study must involve a potentially lifesaving treatment for a serious disease or condition in which you have a short time period, and we’re looking at 96 hours from the time you identify to quality to consenting subject. So again, you’ve not looking at a study in which you have a week to look at this. This is, again, short time periods. Why do you need to do proactive calling? Because you have a very short time period.

As part of this application, each criteria will be evaluated, and you’ll have to justify why proactive calling must be used instead of alternative methods. And that’s why, again, before we do this, because we’re going to go through the methods as well as see, okay, why isn’t this method being used? So again, provide a rationale for why proactive. It is not about inconvenience. That is not an adequate rationale.

Now a huge issue that is part of the criteria, again dealing with the ethics, is that the one thing you do not want to have happen—again, you’re dealing with proactive calling—is you to be the first person to call a potential subject and say, oh, by the way, I’m calling you because there is this lung cancer study. And you have lung cancer. And the subject either says, I don’t have lung cancer, or no, I have pancreatic cancer. Or I don’t have cancer at all, or what are you talking about? What is the process that you are using to verify that the serious disease or condition is indeed accurate, that you have gotten the correct information? And that is, again, a part of this application. What is it?

The next involves—again, we’re dealing with proactive calling and thinking about this in this prospective is about how you’re going to contact the primary care team. One of the concerns about proactive calling or any type of recruitment method, especially when you’re dealing with, again, clinical care, clinical conditions, clinical research studies that impact the clinical care of that individual is about the involvement of the healthcare provider. So how is the study going to contact the primary care team prior to the proactive call? Or if you’re not going to do that, why aren’t you? The justification for why they would not be contacted until after the potential subject has received a proactive call. That is part of the application.

You must include a plan to ensure that the calls made by the VA study team—because, again, as many of us know, there’s the PI, there’s other investigators. There’s the study team, study coordinators. What method is going to be used to ensure that these are made from a non-blocked VHA number. It cannot be made on personal cellphones. The application will include a copy of the script for contacting the subjects and also the number of calls to be made for each potential subject. There’s only so many times you’re going to be allowed to call somebody to try to call them up. You can’t call them 59 times a day, so again that is part of this application.

Part of the application also includes how will you obtain those telephone numbers? What is the source? Again, what you do not want to do is have an unreliable source for how those telephone numbers are going to be obtained. So we are requiring as part of the application, the study, to inform ORD what is your source of the telephone numbers and also if you are going to leave a message. If that is part of the plan that your study is proposing to use, we require a script of the composed message that would be submitted as part of that leaving the message. And also, again, how are you ensuring that you will not include any PHI.

Again, as I reference in the very early part of this call, we are establishing a dedicated SharePoint site. We will be issuing a formal document, FAQs that will being our searchable FAQ database as well as a separate guidance document on this very process that we’re talking about today. Also, the SharePoint site itself will include all the instructions including most, if not all, of everything I’m talking about today. We expect the SharePoint site to be up in less than two weeks. Again, one of the reasons we’re having this webinar today is to give everybody a heads-up on this is what is coming, this is why it’s here, and our rationale in allowing this to occur.

One of the biggest issues that I want to reinforce over and over again that ORD approval does not equal IRB approval. And because of the materials that will be submitted in the application are so detailed, these are the same materials the IRB will be reviewing. So even if ORD, procedure, application, and we approve it, still the IRB has, again, the final authority as the regulatory body for oversight of nonexempt research in terms of the actual protections to ensure that in their view as an IRB, that the safeguards exist to protect the rights and welfare of research subjects. And they’re going to be looking at the same details we talked about. The number of times the research time is allowed to contact a potential subject. The script that is used. And also involvement and/or notification of the primary care provider for the potential subject.

As part of the application, which is not part of the criteria, but we are also going to require, of course, what—and we’ll look for it in the script. What is in your script concerning a call back number or a method for the potential VA subject to verify the validity of the call. Many of you already know this again on the call, but many times, especially with—and I’ve had experience with a potential IRB where the potential IRB will see the call as a result of a study that has been approved by a letter, just like we’re going to send a letter out. And they will call to say, is this really a legit study? We got this letter. Same with telephone calls. There’s going to have to be some type of method where the potential subject can call and say, is this really a legitimate study? We want to emphasize that submission of an application for ORD approval of proactive calling does not equate to ORD approval. And then once that request is submitted, it will be evaluated by ORD.

Now we expect our evaluation of any application, just as we do DocuSign, to occur very rapidly. If you provide all the information, we’re looking at a time of 5 to 10 business days. That’s what we’re allotting. However, we will have a place on the application if there is a time-sensitive request. Let me give an example. For example, let’s say that you have a study in which your site investigator has called and said, okay, your facility has been selected as a participating site; we need you to submit to the IRB within two days. Let’s say it’s a study that’s undergoing commercial IRB for a new approval. Okay, and if you can’t submit within two days, we’re going to defer to the next site.

Alright, you can’t wait 5 to 10 days, and you want to use proactive calling, the investigator. So that is where on that application it will say, this is time sensitive, and we will work to get that turned around within 24 to 48 hours. So you will have that option on there to also deal with that. So that’s going to be the timeframe that we’re looking at. In terms of the evaluation of the request when we make the determination, we will send that back to the requester including the VA principal investigator, as well as the VA Facility’s ACOS/R&D. A copy of that final evaluation, whether it be approval or disapproval must be kept with the VA Principal Investigator’s study file.

And so with that, and we wanted to have plenty of time for questions, we will have a recording of this session, and we will include a copy of the memorandum. But again, the under secretary’s memorandum will be posted on the website by tomorrow. The webinar itself will probably be posted within 7 to 10 days. We have an archive of sites, of all of our webinars at the link that you’ll see on your slide. I want to emphasize here for proactive calling is again it’s a mechanism that can be used, but it will not be used frequently. We take it very seriously in ORD, veterans rights, VA subjects’ right to not receive a lot of solicitation. And so that is why the criteria is as stringent as they are, as detailed as they are, and why again this is not something that’s just something that you can just, okay, sounds good, let’s go for it. So again, carefully think about it before you do it. So again, that’s why we have it, and that’s why again the Acting Under Secretary of Health approved this as a mechanism that can be used.

And so I’ve included some references at the end of the this slide presentation. I do want to say that we get a lot of—there’s a guidance which we issued in 2017. It’s called Draft ORD Guidance on the Use of Electronic Mail and Electronic Text Messaging for Recruiting and Communicating with VA Subjects in VA Research. And now that was a draft guidance that was developed in collaboration with many, many different national program offices. That includes VHA privacy, OIT, ethics, Office of Research Oversight. The information in that draft guidance is still incoming. It has never been finalized, but that information indeed is very valuable in terms of differentiating and giving examples of what can and cannot be put in, for example, a recruitment email when you’re dealing with sensitive versus non-sensitive information.

The other thing I want to talk about before I open this up to questions and answers is about the fact—and I want to go back to a slide, and that involves this about approval. So let’s say that ORD approves the request, and the IRB says, okay, we’re not going to allow it. Again, that’s a no. But I also want to talk briefly about something that’s not on this slide, that’s about letters. As part of our current policy, we require—and this is, let say that you’re not talking about cold calling. And we get a lot of questions about this. And let me go back to the policy itself. Okay, during the recruitment process an investigator is required to make initial contact with potential subjects in person or by letter prior to the telephone contact.

Now ORD does not require the potential subject that one is seeking to get consent from to say, I want to opt into receiving the recruitment telephone calls. The policy is silent on that, and that is by design. We do not state that. All we require is that the letter be sent if you’re not doing an in-person contact, if we’re not talking about proactive calling. There are some IRBs that state that they require opt in, that if an investigator sends a letter to a potential subject to say I want to be able to call you, that that IRB has a local policy and procedures saying, well, the subject has to opt in saying I want to be called in. That is not ORD national policy; however, if the IRB requires it, the IRB local requirement has to be followed. But we also wanted to reinforce that as part of our call today.

So with that said, I am going to stop sharing my screen, and at this point, we have about 20 minutes for questions and answers. So thank you for listening to this part of the webinar, and I’m going to ask Kate to help me. And we’ll do questions and answers.

Kate: Alright, and if you can see my screen, we have the first question showing.

Dr. Karen Jeans: Alright, thank you. And the network is slow today, everyone, so I was telling—okay, “Does the current directive allow for the use of email for initial contact? The prior slide indicates the letter is hardcopy or electronic.” Excellent question. The answer is yes. When we say letter, a letter could be written, a letter can be electronic. So the current policy, 1200.05, does not prescribe that the letter has to be in “hardcopy”. However, again, when you’re talking about emails, if you send an email saying I want you to be in this study because I understand you had COVID-19 before, that is sensitive. So that can only be sent through approved encryption or through Azure RMS.

Now the problem with Azure RMS is while you as a study team can send that to potential recipient of that who would be a subject in the study, if that individual does not have Outlook, they can’t open it. And so that’s the problem. However, in that draft guidance I referenced, you’re going to see examples of non-sensitive types of recruitment messages that can be sent by email. And so I will refer you to that, and that’s one of the reasons we wrote that draft guidance in 2017 to give examples of how this could be done in a non-sensitive manner. You’re not going to be able to name the study, but it will provide some information on that. So yes, the answer is the letter can be hardcopy or electronic. Thank you. Next question.

Next question: “Do you have an example of a specific study that the proactive calling would be approved for?” I’m not going to get into an exact example, except I could use a generality. Okay, let’s go hypothetical here for a second. Now this is not a real study. But let’s say we have a study in which it’s COVID-19. You need to get blood from the study subjects within 48 hours. Let’s say 72 hours. Let’s go 96 hours—no, 72 hours within the time they receive the notification or the lab states, oh, by the way, you’re positive for COVID-19. Now there’s no way possible that you’re going to be able to get a letter out there in time. It’s not feasible.

Now would that study result in lifesaving therapy? I don’t know. It depends on what that blood is being used for, but that is the type of scenario you’re talking about, that you need to do a drug within—you need some type of study in which therapy has to be administered within 72 hours of the time of COVID diagnosis began. And it’s all outpatient. And they have to have blood drawn first before they can even begin the therapy to see whether or not they would be eligible to do a screening test. And that’s a variation as I’m thinking of an example here on the fly. That is where you would probably be able to get a justification and get approval for depending on what’s in the application. So again, it’s these very short timeframes where they’re not going to be coming into house. It would involve a potentially lifesaving therapy. And again, in this example, COVID-19 in which it would not be feasible.

And again, justification would have to be made in terms of why is this potentially lifesaving, and why are other methods not used? But that’s the type of study we’re looing at. Thank you.

“For the measures put in place for individual’s protection, are those to be initially designed and submitted by the researcher based on the type of study and to be part of the ORD process? Or are those protections going to be generalized and unequivocable?” They are not going to be generalized and unequivocable, and they’re not going to be listed in some central location. These are specific two the study, and that’s why those criteria that are met that we listed, those nine criteria include privacy issues and ethical protections. And so they are indeed specific to the study, so every study will not have the same answer because every study doesn’t have the same type of design. So excellent question, they are specific to the individual study which as a protocol is individual. Thank you.

Oh, excellent. “If people have questions is there an email address or website to which they should be referred?” Absolutely. On the last side it says vhacoordregulatory@va.gov. Please send questions regarding proactive calling to the VHA ORD regulatory mailbox. We will ask that you put in the title subject line proactive calling because there are other individuals besides myself that are going to be involved in answer questions regarding proactive calling, and that way we can get those vetted appropriately. We receive anywhere from 500 to 1000 different types of queries through that regulatory box a day. And so that is why if you put it in the subject line, we’re able to deal with it more expediently and efficiently. Thank you.

“Can we assume—,” first of all, don’t assume. I’m going to start with that. “Can we assume that if a CSP study has been allowing proactive calling of potential subjects, it has been vetted and approved by ORD?” No. No. No. You cannot assume that. “It is NOT a treatment study, but a COVID related study.” Policy is in effect. I want to emphasize that. Policy is pure, and so you cannot say, well, we’re doing this, so therefore we’re going to look the other way. So as ORD is relaying to you today until the under secretary signed this memorandum that, again, allows this exception with the formal ORD approval process that I’m relaying to you, use the proactive calling unless the subject has already said—and I’m using the word subject because they would have been a subject in another study, has already indicated I want to be called about future studies. Then that is not in alignment with 1200.05. So no. The answer to this question is no. Thank you.

“Will IRBNet generated documents be updated to easily track requests for proactive calling?” That’s an excellent question. I will need to defer to Dr. Klote on that. And this is actually a wonderful question that we will put in part of our FAQs. So I cannot give you an answer of how exactly that will be done today. I will defer. But thank you for that question, and we will put that as part of our FAQs. So thank you whoever presented that question.

“Should we include a script for it someone else answers the phone?” Well, again, this gets back to how do you verify that the individual is the person that you’re speaking to, the phone. So let’s say again for example of today’s presentation that you want to call me, Karen, to ask me about a COVID-19 study where, again, you need to draw blood on me within 48 hours after I’ve received my call that I have COVID, for potential oral therapy. Alright, that I need to be given within 96 hours of receiving that. So as part of your script, may I speak to Karen. Okay, if it’s not, then you say—it goes back to okay. What you do normally. If you can’t speak to Karen, then you hang up the phone. Oh, she’s not here. That’s it. That’s the end of the call. So that’s what you would do with any type of telephone call. If that person is not there, is not available, you hang up the phone. Thank you.

“Can the R&D office submit the request to ORD for proactive calling, or does the researcher need to submit the request? Or neither.” It is the study team, it’s the researcher. The investigator is going to have the information in terms of the specifics of all these different criteria. However, we want to reinforce that our determination is going to go back to the ACOS as well as the researcher and the study team. Now with that said, even as a result of as we’re piloting this, we may change and modify as we go just like we did with DocuSign. So what I say today might be slightly modified, but it is an investigator submission. Thank you.

“Will study teams be able to talk to LARs using proactive calling?” Again, it’s potential for calling VA subjects. So if surrogate consent is going to be used, again, you would come in and that’s your plan to contact VA subjects with a surrogate, so again all the criteria would be met. And so it has to be met in order or ORD to approve proactive calling. So it is not prohibited, but again all the criteria are going to have to be met. Thank you.

“Does a potential participant have to give written permission to be contacted for a future study, or may it be verbal?” Well, you’re talking about consent, but you’re also dealing with HIPAA authorization. And so you’re not going to waive a HIPAA authorization when it’s—again, we don’t have such a thing as a verbal HIPAA, so you’re going to have a waiver of HIPAA authorization in terms of contact for a future study. Theoretically, you could do a waiver authorization of informed consent, but again the criteria would have to be met. As a biobanker and as a database banker, it is not wise to house verbal consents and waivers of HIPAA authorization because the need to track, especially if you have a subject—it’s happened many times in the world of biobanking and research databanking where they will—where I subject may say, I did not agree to this, and you don’t have anything there that has their signature. So yes, if the criteria’s met, could you do a waiver of document of informed consent and a waiver of HIPAA authorization? Of course you cannot disclose outside the agency PHI with that alone if you’re doing a databank or biobank of identifiable file specimens or data. But with the criteria met, it’s possible. It’s not recommended. Again, we’re talking about policy versus recommendation.

Next question: “What is the process to set up a single, centralized phone number for subjects to call that can utilized by all research team members as opposed to a desk phone?” That is outside the authority of ORD. That is something you can actually set up in your different facilities if it’s possible. I cannot answer that question. I don’t know the answer to that. We might can followup on that. I would need to ask the telephone services for the different facilities, but I don’t have that technical question today. So I will defer on that.

Next question: “Is contact allowable for potential recruitment through MyHealtheVet?” That is unequivocal no. As I discussed during the webinar, the Office of Connect Care is responsible for MyHealtheVet. And while they allow and indeed have supported VA research, for allowing the use of MyHealtheVet to communicate with subjects who have already consented into the study, it is not permitted, unequivocally, for potential subject recruitment in VA studies. And that is because there is not an opt out or opt in option on the current platform. When that capacity comes into play, that is when it may be allowed. I cannot speak for OCC, Office of Connected Care. But no, it is not permitted. ORD's guidance document, which is also included and was developed in collaboration with the Office of Connected Care, also reinforces that. And that is a reference which is included on this webinar slide. Thank you.

“We use the NCICIRB. For most site-specific issues our local R&D may address them. I assume I would have to contact the NCICIRB, but would our R&D have any part of the decision?” The IRB must approve the use of any subject recruitment method for proactive calling. That is part of the IRB approval criterial. It is there responsibility in terms of ensuring that the ethical, safety, and welfare of subjects is protected. It is also part of the reason scripts are evaluated is to assure that there is no undue influence or coercion as part the script that is to be vetted. So, again, the IRB would have to approve the use.

Next question: “If MyHealtheVet cannot be used for emailing—,” it cannot be used for email for subject recruitment. Let me clarify. “—were does one get the email addresses of potential subjects? Would that information be in where their address and phone numbers appear? I don’t recall if I remember seeing email addresses there.” Again, there’s different sources of emails, email information depending upon your data source. Again, it’s outside the scope of this call today to discuss what are potential email sources, but that can be in part of the application, where are you getting those email addresses from?

Next question?

Kate: And it is now 3:56, so this will have to be our last question.

Dr. Karen Jeans: Thank you, Kate. “For a multisite study, can one PI apply for all sites?” That’s a very good question. The answer is yes based up on current model. But here is the deal, and it’s just like when you’re doing a central IRB application. You have the master application where all sites use that mechanism unless they deviate through their local site application the same way here. If one PI, the study chair local site, the overall PI applied for all sites, all participating sites must use the same type, the same criteria that is used to meet it. So the answer is yes.

And with that, that will be our last question. What we will do is take any unanswered questions, Dr. Klote and I and other who are working on this project in ORD, we’ll look at the remaining questions as we develop the FAQs that will be published with this. I do want to also state that before the SharePoint site does to live in two weeks, if you do indeed have a study where you believe you that proactive calling is indeed something you wish to seek an application for, you may go ahead now and write the VHA regulatory box, proactive calling, and we will end you the criteria of what will be required to be submitted as part of the application. So just because the SharePoint site is not active yet does not mean that you have to wait. The memo is not in effect. The webinar we’ve not given, and again we will have all of this available very soon. But you can go ahead and request an application from ORD, and we will give you the list of materials to get while we wait to get the SharePoint site.

With that said, again, I want to thank you all for being on this call today. This is a lot of information. The memorandum from the under secretary will be posted by tomorrow. If you have questions, please send them to the VHA regulatory box with the line proactive calling in the subject line. And thank you so much for your commitment to VA research as we all work together during this time. And so with that, I’ll hand it back to you, Kate.

Kate: Alright, thank you so much, everyone. Just a reminder that there will be a survey that pops up on your screen after you exit. And thank you so much again.