Jessica Kroll: Overview of why changes were made. A description of significant changes, a live demo of the new continuing review forms. And an update on what’s next. Next slide.

So why change the continuing review process? Looking back at our dashboard data from 2022, we identified that the VA Central IRB reviewed over 1,000 PI and LSI continuing review packages and IRB med. Given that volume, and that it’s been increasing we knew it was time to re-evaluate our current process. And identify areas for improvement and efficiency. During the evaluation we identified a number of opportunities, one of which was creating a continuing review submission process that fits within IRB med. But more importantly we were able to revise our submission forms for better useability and improved instructions with a goal of reducing administrative corrections and revisions. So revising the submission forms will also provide for a more efficient experience for research teams and the central IRB reviewers. Next slide.

So additionally we identified an opportunity to reduce duplication of reviews between essential IRB and the local research sites of select content. For instance the central IRB was spending time verifying study personal training, credentialing and annual financial conflict of interest. However this is all managed by the local site and was duplicating some oversite efforts, which often led to delays and processing continued late reviews. A major change to our forms revisions included providing an easier means for the PI to review, compile and present LS find continuing review information. And to a complete PI continuing review package. With the form changes, the PI will be able to present comprehensive information for their multi-site project, representing all participating local sites. Lastly, taking a deep dive into our continuing review process and forms has led the way for other central IRB process and form updates, which will be coming soon. Next slide.

Now I’m going to pass this over to Mary Acker, which she’ll provide a description of the forms and process changes that we’ve made.

Mary Acker: Thank you so much Jessica. And I want to thank everybody for joining us this morning for this webinar. We’re very excited to share with you all that we’ve been working on for quite some time now. Next slide please.

So a quick peek of the forms that will be used now for continuing review. We will still have the form 115A principal investigator, continuing review application. Form 115B local site investigator, continuing review supplement. New form 115D which is the protocol deviation log. Form 115E adverse event log. And we will no longer be using 115C, which is the alternative documentation of financial conflict of interest. No longer will we be needing that. And just wanted to let you know that we are going to have a live demo of each of these forms. So I’m just going to touch upon the changes, but you’re actually going to see the forms in more detail. Next slide please.

Okay, so again to echo Jessica. We wanted to better align the principal investigator continuing review application. And the local site investigator continuing review supplement, so that all the study data can be presented overall, the PI will present it once compiling it from all the local site forms. The sections now align so the 115A sections are going to align with the 115B sections. This is going to help tremendously readability and usability really. And it’s also going to enable more accuracy and it will be easier for the principal investigator to compile, all the study wide data. Deviation logs are going to be – deviation and adverse event logs are going to be required to be used. They are – they’re going to standardize event reporting. And we will no longer have the ability to report events within the continuing review forms. Again, this is to standardize and provide better accuracy. And it’s going to be easier for the principal investigator to compile all the data from all the local site investigator supplements.

Added to the 115A, the principal investigator continuing review application, is a table that will compile all enrollment information. Again by gender, race and ethnic group. And it will still be required in the LSI supplement, but the PI will compile all the data, so that it is easily seen study wide. Next slide please.

So the old section two, in the 115A and the 115B is going to be very, very different. And I think quite a welcome change. So we will no longer – there will no longer be the ability to add or remove non-key personnel. Rather, there’ll be an attestation later in the form. Where the PI or LSI will ensure that all staff are currently credentialed, trained to be working on the project. Key personnel additions and removals, as always, are required through an amendment. And this really is to ensure that there’s appropriate replacement oversight of the project when removing or adding a new PI or LSI.

No longer is the requirement to mark the personnel obtaining informed consent. And another welcome change we are not requiring human subject protection training dates. Again, as I mentioned before there will be an attestation from the principal investigator or the local site investigator that all personnel are up to date on their local training requirements, prior to the submission of the continuing review. Next slide please.

As I mentioned before, we are no longer using the form 115C. The financial conflict of interest supplement documenting that the review has taken place. Rather there’s an attestation section for the PI or the LSI that all personnel serving an investigative role have, in fact, undergone their required annual continuing review. I’m sorry. Their annual financial conflict of interest review prior to the submission of the continuing review. So we have removed the requirement to upload local facility annual FCOI documentation. And the only financial conflict of interest documentation that must be provided to the central IRB for review is if, in fact, there is a financial conflict of interest management plan for an individual on the project.

So if there is no apparent conflict of interest, there’s no existing management plan, there is no financial conflict of interest documentation that must be submitted with the continuing review. Study personnel credentials – again that’s section two is no longer – there’ll be no check boxes needed. Because the principal investigator or the local site investigator will be attesting that all personnel are appropriately credentialed at their local facility prior to the submission of the continuing review. Amendment listings. No longer required. That has been removed from the 115A and the 115B. As all the amendments are easily contained within IRB net. So again as Jessica said, we are trying to remove duplicative tasks and reporting. Next slide please.

Okay another big change. The VA central IRB review and determination of local site investigating continuing review packages. What will be different, the continuing review determinations are changing from an expedited review. With an approval to an administrative review that will be acknowledged. You will really see this change in the LSI package review details in IRB net. And the LSI continuing review determination letter. So the determination letter for the LSI continuing reviews will be acknowledged. But please note that all the continuing reviews for local site investigators will continue to be approved, but it will just be under the principal investigator continuing review determination letter. Next slide please.

Okay, with that said, I am going to turn this over to Mikaela who will provide the live demo of the forms we are just talking about. Mikaela take it away.

Mikaela Myers: So here we go. Since there are a good amount of changes to these forms. We did want to show you exactly how filling these out is going to look like. And so I’m going to walk through the process that we think is going to make the most sense for submitting these. So I am starting with the 115B, which is the LSI application. Because this application is going to inform the PI application. So we’ll walk through that later. A couple notes that are highlighted in the instructions, but the due date has not changed, so it’s still 60 days prior to project expiration. But the LSI will need to complete this application prior to the PI submitting. So even though everything needs to come in at the same time, it’s really the LSI that needs to complete this form before the 60-day expiration due date. So that said, we will go through this. And just a note too, as always this instructions page can be deleted when you’re ready to submit to us.

So you’ll see some changes here to section one, just some wording and formatting changes mostly. I do want to highlight that the board reference number here is that same four-digit CIRB number that you’re used to putting here. We’re just being more consistent about the needing of that. So and the terminology.

Okay so section two. Not a lot has changed here. But just to highlight that this needs to be completed, again for the LSI site. So really taking note of what the current project status is for that local site.

Again, answering for the local site. If there is no enrollment, then you can check n/a above here. This section has sort of been formatted and revised a little bit, but it’s mostly the same. So we’ve kind of redefined enrollment here. And we want all of the same data we were collecting previously about enrollment at the local site, screen fails and things like that.

Okay, so a couple changes to this section. We have expanded it a little bit just to further align with FDA standards. And as indicated here if these data are not collected for the approved IRB protocol, then you can check n/a here. But this is really information that does align with FDA. And should be collected, unless indicated in a protocol.

Okay. This section is mostly just reformatted. You’ll notice that some of the sections have been sort of moved around. And that’s to better align with the PI application so that they mirror each other for easier compilation later. So this section really hasn’t changed a whole lot, except for some better descriptions and reformatting. And again this is site specific when you’re answering these questions.

Section six. So the LSI is going to indicate as they always have, the dates of all of their approved documents and which versions they’re using. Now this information is collected so that the PI when they receive this application for the compilation of theirs, they can go in and verify that all of the correct documents are being used for study.

So this is similar to what you’re already used to. It does include any site-specific events and reports. I will show you, as Mary mentioned, the new forms that we’re using just to standardize the data that we want to collect in terms of deviations and events. So I’ll just jump into – dive into the 115D. So this is the protocol deviation tracking log. It – like Mary mentioned, we created this document just to really standardize what it is that we needed from researchers in regards to the description and the actions that we’re taking, as well as any risks that might have occurred for participants. So we don’t want anything more than this. We don’t want anything less than this. So this is really to standardize the information that is collected from you guys and sent to IRB reviewer or the IRB so that they can ensure that the safety of participants is still appropriate for the study.

And I’ll just show you too, that if additional lines are needed you can click the little plus sign here. As well as click over here and add using the tab key. And then I will show the 115E which is the new adverse event tracking log. Just so you know, same for the critical form. But you’ll want to make sure you’ll include all of your site information here as well as the site named here. And that’s for the PI to be able to compile this list later, which I’ll talk more about as we get to the PI application.

Same thing, we’ve outlined all of the data that we need from study teams regarding the description of the AE. Whether it was serious related, unanticipated, the outcome and the action taken by the study team. So after the event occurred, what was the outcome and how did the study team address the event. So same thing, we don’t want any more than this. We don’t want any less than this. So just making sure that this is completed as requested in the questionnaire. So – and same thing here if you need to add additional rows. You can do the tab function or the little plus sign here.

So I’m going to jump back to the 115B which is the outside application. And these are the questions that are associated with the 115D and E. So if those forms are needed to be completed for the local site investigator, you check yes and you upload the forms in addition to the application.

So this section hasn’t changed a whole lot, but we do want to highlight that there is a new RCO audit workspace in IRB net. And so we are acceptable that if the local site is using that. So you answer this section based on sort of any audits that have occurred. And if you’re using the workspace then we can go in and see the report, or at least the overview of the report. We can’t actually see the physical report. But we will be able to see sort of the – the outcome. And if the local site is not using the workspace, then we are still accepting summaries. And we have highlighted here that we are not accepting the audit tools. We don’t know how to refute those. Those are really meant for the RCO to make a determination on the audit. So we are accepting tools, but we are accepting summaries from the RCO. So either the summary or the workspace as well can be submitted to us.

So as Mary mentioned this section has been updated quite a bit. Such that no removals or additional to study personnel can be accepted at the time of continued review. So this section is really meant to include all those that are currently approved to be working on the project. So again we’re talking about the LSI site submission. So they should align everybody at the LSI site that is working on the project. And LSI should attest to all of these things by checking the boxes here, like this. And listing all of the – all of the personnel here. And same thing, you can add additional personnel by using the tab function or the little plus sign.

So this section is just listing off what’s included in the package. So checking any of these boxes that are applicable. For example if you’re uploading the form 115B, you should check that box. As Mary indicated we are no longer monitoring the 115C, which was previously the – the FCOI [inaudible] from the local site. So we no longer require that documentation. However if there is a management plan associated with an FCOI or SOI review, that plan should be submitted as part of the package. So you would check this box here. And it would be reviewed by the reviewer or the IRB.

Okay and then this section is just assurances. So again LSI is checking all of these boxes to ensure that they’ve completed the form accurately. Okay. I’m going to jump over to PI application now. So this is the 115A. Similar to the 115B there are instructions up here that should be deleted prior to submitting. It does note that several of these sections are going to be a compilation of the LSI application. So again just stressing the importance of having the LSI submit to the PI in a timely manner so that the PI can ensure that they’re submitting the – all of the local sites and the PI submission prior to that 60 day to date.

So very similar to the other application. Just a note that we have included a question about FDA regulations. So if this study is FDA regulated you’ll check yes here. If it’s not, you’ll check no. Same thing, word reference number is referring to that four-digit number. So that’s what we’re looking for here. Okay so section two is going to – as it has previously is going to refer to the entirety of this study. So you know there might be one site that is close to enrollment, but one site is still open to enrollment. So this should really encompass the entirety of the study. Where – where the project is at in terms of the status. If it’s close to enrollment, still enrolling at some sites should still indicate that it’s open to enrollment.

And then this section is three through seven. There’s an additional note here, just reminding the PI that these sections are really meant to be a compilation of the LSI application. So this section here is going to ask about you know, the LSI. The local facility and then any enrollment numbers from that site. So this should list out all of the sites and the enrollment numbers for those sites. Same thing, you need to add more plus sign and there are instructions for that here as a reminder.

And I’ll just note too that it is really the PI’s responsibility to ensure that if any of the sites have gone over enrollment, that should be noted here, and the PI should take note of that. And you know that really sort of falls into this idea that it is a multi-site study. And the PI does have a main responsibility for the overall study. So they are really responsible for all of the local sites that fall under the study. So that’s sort of more closely aligning with that multi-site role of the PI.

So section four. We talked a little bit about this in the LSI. So I’ll just sort of briefly say that again this is a compilation of all enrollment site wide. Or you know all of the sites, so this should be a compilation of all the sites. And the data associated with gender and ethnicity, race, etc.

Section five is meant to pick up on any trends that are occurring study wide. So again, answering these questions in terms of study wide. All of the LSI sites, were there any study wide recruitment \_\_\_\_\_ 0:29:24. Are there any complaints? If so, you know are there any trends about those complaints across the entirety of this study. This is to help both the LSI and the IRB reviewer for the IRB to determine if you know, any type of intervention or changes are needed to the study to address complaints or \_\_\_\_\_ 0:29:46 across this study as a whole.

So as we talked about, as part of the LSI application the PI is going to complete this section indicating the dates of the forms they’re using, any waivers they have. And they are asked at the end here a question for – to attest that all of the local sites are using the correct documents for the study. So this is a requirement of the PI. And they should ensure that this – that all documents are up to date and the correct versions are being used by all the local sites.

So this goes back to those two forms that we have. So any type of reporting that is needed. So I’ll just open these again so that we can sort of revisit them from the PI perspective. So the same forms are going to be used for the PI. It’s really just the compilation which essentially means a copy/pasting for the LSI applications. I want to highlight here in the instructions that if there are any questions about what needs to be reported a good tool for answering those questions would be the table of reporting requirements. So that’s a great place to go. That also is being revised currently, so that should be up and running pretty soon, I think the end of June here. So that’s a great place to go if you’re unsure of what needs to be submitted at the time of continued review, versus what requires immediate reporting.

So when the PI goes to fill this out, again all of the investigator information indicating that this is for the PI. And then just the copy/pasting of what is pulled from the LSI reports. We do recognize that’s going to be a lot of sort of administrative copy/pasting. However this information is really valuable for the reviewer and IRB to take a look at, to notice and pick up any trends that are occurring throughout the year since the last continued review or since the \_\_\_\_\_ 0:32:39.

So this is really going to help us pick up on the trends across the study, to really understand is intervention needed here. And – or any changes. And same thing with 115E, which is the adverse events. Same thing. So just checking that this is for the PI, copy/pasting the sites, actions, etc. We imagine that you’ll need to add additional rows for that. So again just tab or the plus sign here and adding the additional rows.

Okay so section eight same thing as the LSI. We are accepting the workspace for any PI specific audits that take place. So if there’s an RCO audit that was completed in IRB net, we can take a look at that workspace. And you’ll indicate that here. Otherwise, we will accept the summary, but again please note RCO audit tools. We don’t know how to look at those, so that’s really not meant for us or the IRB reviewer. That’s really meant for the RCO. So submitting the summary is of the findings is what we need.

So for the team members. Same thing. Just attesting to all of these things here by checking the box like so. And for the PI this is meant to just encompass the personnel that are at the PI level. So you do not need to include LSI’s in this list. This is really just for the PI personnel lists. So the listing the personnel that are currently approved to be working on the project. And again no changes, no removals, no additions at the time of continued review.

Okay. Section 10 is we’re naming it progress report. It’s the same abstract that you’re used to submitting, really no changes here or just rewording it so that it says progress report, that seems to better align with what it actually is rather than an abstract. So this is just a summary of all of these five and potentially six items of where the study stands. Sort of an overview in your own words of where it stands on all of these things. Okay. Section 11 is just indicating the contents of the package. So clicking these boxes. Indicating you know, any of these forms that are included and again just to highlight that we don’t need that form 115C, but if there is a management plan to manage an FCOI or COI please do submit that and check the box here that that’s included. Okay.

Same thing, the PI should check all of these boxes to indicate that they attest to these things. Okay. Stop share. So I’m going to send it back to Jessica and we’re going to finish up the slides and Jessica is going to talk a little bit more about what’s next.

Jessica Kroll: Thanks Mikaela. So now I want to talk about some important dates that are coming up. So given all of this new information, tomorrow June 14 the new continuing review forms will be uploaded to the central IRB net forms and templates library. And will be available for use. I do want to note that because this is going to be a transition, we will keep our old forms temporarily in essential IRB library. To accommodate any continuing review submissions that are in progress right now. We do recommend that the PI work with your local site investigators if you are planning to submit a continuing review during this transition period, to ensure that all sites are on the same page as to whether or not they are going to be submitted the new form or the old form.

If there are any questions or you need any assistance while compiling a submission during this transition time. Please reach out to Mary or Mikaela for support and we’re happy to work with you, we understand that we’ll need to be flexible during this time. And email communication is going to go out to all local site liaisons and central IRB researchers that’s going to include a summary of these changes and information that was provided today. Then starting August 14 the central IRB will only begin accepting the new continuing review forms. So any package that’s submitted with an old form will be returned for the new forms to be submitted.

Again if you are concerned that this deadline may impact your continuing review submission, please reach out to Mary or Mikaela for support and we’re happy to work through it with you. Next slide. Thank you.

So that’s the wrap up for continuing review. But before we want to move into questions I wanted to talk a little bit about some additional VA Central IRB updates that are coming. So all VA central IRB forms are undergoing revisions and updates. So between now and July we will be releasing those new forms out to the field. So stay tuned for future communications from the Central IRB regarding the release of these new forms and process changes. In this way we communicated for the continuing review, we’ll be doing emails. We’ll be updating our website and we’ll also be doing another webinar later this month. And always, just to remind everyone, as we’re going through this transition and to prepare for the release of these new submission forms, continue to always download forms directly from the forms and templates library and IRB net when they are needed. And this is just to ensure that the current version is going to be used and submitted with the package. After that August 14 deadline, if we are receiving our version of the forms, they will be requested that the new form be submitted. Next slide. All right. I am ready to take some questions.

Unidentified male: If they could read out each question before we get started answering them?

Unidentified female: Of course. Thank you. So first question. Can you please define what is meant by key personnel? So key personnel, those who are named in the protocol and are essential to carrying out the work of a project. It’s typically those responsible for the scientific design, conduct and execution of the research in a measurable way. Key personnel can include PI’s, LSI’s or those in an investigator role who devote a measurable effort to the project. But I would also like to note that there can be local site requirements or definitions of key personnel, which is important that the study team follow their local policies. But I do think this is a great question. And I think we will look to add a definition to our forms to provide that additional guidance to the study teams. So thank you. Next question.

Can non-investigator key personnel still be added or removed at continuing review? No. So the continuing review forms will no longer allow for the addition or removal of personnel at continuing review. Next question.

If an investigator who is not an LSI is leaving a project, does the removal require an amendment or list the removal on form 130? So first I’ll note that form 130 is the annual status report that’s completed for a PI that has a project that doesn’t require continuing review. The annual status report form has been revised to align with the changes that were made in our continuing review form. So in the same way that you can’t add or remove personnel from a continuing – at the time of continuing review, is going to be the same at the time of annual status. So you will not be able to add or remove an individual when submitting form 130. Next question.

I understand the protocol deviations and adverse events will no longer be listed on the continuing review form. And so 115D and 115E going to be required in every CR submission even if there are no adverse events or deviations? So no. On the continuing review form there is going to be a question that will ask if there’s been any deviations. If you check no, then you can continue going. If you check yes, that’s when you’ll be required to submit these. So if there are no adverse events or deviations the 115D or E is not required.

Please clarify the statement about IRB continuing review. Will the IRB acknowledge receipt of the package, or will the IRB acknowledge, rather than approving continuation? The statement was not clear. So for LSI continuing review supplements, in the past we had processed them as expediting and approved. And that at times caused a lot of confusion and it didn’t truly line up with an expedited review procedure, according to the regulations. Because the PI project or the PI continuing review is the one that the IRB is reviewing and approving. The LSI continuing review applications are really a supplement to support the information that’s being compiled and presented into the PI continuing review.

So all LSI continuing review supplements are now going to be an administrative review and they’re going to be acknowledged. And then I would like to note too that the LSI’s are being approved under the PI application. So they are being approved, they’re just not being approved in the package they’re submitting as being approved under the package that the PI submits. Next question.

To clarify on the form 115D will the PI have to list all deviations by all of the LSI’s? Yes. So the PI will need to compile and present all LSI deviations on the 115D. And that will be the same or the 115E.

Are the adverse event and deviation logs intended to list all events through the year, or only those not previously reported via a stand-alone package? So it’s mean to list any event that occurred within the last reporting period for that continuing review. And it should only list items that are – that are not being resubmitted. So it should only be first time deviations or adverse events. If something was submitted separately, typically that would mean it was submitted as not compliant, or as a \_\_\_\_\_ 0:47:27. So those would not need to be listed on these forms.

When does this take effect? I have a continuing review going on now. Though the LSI too acknowledge. So I put in the dates we’re going to be releasing the forms tomorrow. So there will be a two-month transition period and all forms will be required to be used by August 14. But if you’re in the process of completing your continuing right now I would expect that you can use the old forms. In terms of the process change, we will begin processing as an administrative for LSA continuing reviews this week.

With the addition of form 115D, this should be approved by the sponsor of the setting to make sure it’s a protocol deviation. I am not quite clear on that question. But you can send an email to me and if you want to provide a little bit more context, I’d be happy to answer that. Next question.

Will the PISC 115A get in VA central IRB approval or it will get an admin review and acknowledgement? The PI continuing review will get the approval. They’ll be either convened board an expedited approval. The PI will not get the administrative acknowledgement. That’s only for the LSI supplement.

An AE reporting, no intensity and related just yes, no what about possibly or probably. I believe that was on the adverse event form. There’s a question to identify that was unanticipated related and a level of seriousness.

Is the 115C discontinued completely or just for CAIRB continuing reviews. Will it still be required for initial submissions? The 115C is discontinued completely for continuing reviews. There’s also the form 102 for the ACOS review. And that is still going to be required for all new projects.

Does the change to listing study personnel also change the requirements surrounding listing pharmacy stuff? I would take this question to your local research office as the local research offices have a different policy than we do at the central IRB regarding how pharmacy staff need to be listed on the project.

Part of the 115E. There’s no \_\_\_\_\_ 0:51:02 of numbers of events. Each event per participant is being listed. So there are two occurrences of nausea, that will be participant one. Nausea participant two, nausea. Yes that is correct. It will be listed by participant.

What sites do that are a lead site and an LSI site. So in terms of continuing review there’s been no change in this aspect. You are a PI who also has an LSI. The LSI will still need to complete their continuing review supplement. And then the PI will compile all LSI’s even their own and reporting the PI continuing review application.

Well LSI continuing review submissions that are acknowledged receive letters generating that will include the expiration date or the annual status report date? Yes all LSI continuing review letters will be acknowledged, and they will include the expiration date of the PI. However, LSI’s do not have an annual status report date. Only a PI will get an annual status report date. And in those instances LSI’s do not submit anything to the central IRB. It’s only the PI who submits the annual status.

How does new team members receive email notifications of webinars and education? And I guess Parker speak to this, but I do believe they go out to all researchers from the group. And if possible, and if we have information in advance, we’ll include that in the central IRB communications on our website. Parker.

Parker: Yeah, you can email – a group that controls the List Serve. But generally all of our announcements are on our web page, so you can see any new webinars there. I would have to refer back to your team if you know who controls the webinar list serve.

Unidentified female: Okay. yeah we can look into that and make sure it is reaching everybody that it should be.

Parker: But if you’re on that List Serve and you receive notification about this, central IRB etc.

Unidentified female: Thanks Parker. Did you say there were changes to the conflict of interest for all investigators? So yes as I mentioned some of these changes in the continuing review process are going to be reflected in our other processes. So we will be having a webinar on June 27. It will be sending out some new communications to all their researchers informing them of this change across the board. So in the same way that Mikaela and Mary indicated that conflict of interest is going to be more of an attestation, versus us collecting the local documentation that’s going to apply to amendments of new investigators, it’s going to imply to any investigator being added to a new project. But ultimately yes, there will be an attestation and the only documentation that we will require for conflict of interest is if there’s an actual management plan that needs to be submitted.

Unidentified male: The documentation of that, because it is an IRB responsibility as it’s a research office responsibility and the R&D committee oversees that. the IRB certainly needs to know if there are financial conflicts of interest. But the only change, and we’re getting verification from the investigator and from the research office of the initial review. That the documentation is something that’s oftentimes held up applications and we’re simply not collecting that documentation anymore.

Unidentified female: Thank you. Only key personnel will be listed on the continuing review form. Does that mean the personnel that’s between that and the project cover sheet will be inconsistent? Ideally the project cover sheet should be in up-to-date current document reflecting who is currently working on a project. So in the continuing review form if you’re listing all staff that are currently on the project, that should mirror the project cover sheet.

Unidentified male: If I could step in again. Changing the practice and so for instance on the website ORD list individuals who need to have annual training or every three training. That requirement continues, we’re just not asking for the dates on the form. And or documentation in the application. So again the policy is not changing, the requirement is not changing. And in the VA requirements for training protections includes more than just investigators. It includes the individuals who may be collecting informed consent, other people who may be handling confidential information, etc. so none of that is changing. We’re just not collecting the dates with documentation in our form.

Unidentified female: Thanks Don. And it looks like we are out of time. And if there’s any questions that I have not been able to get to, we can answer those offline.

Unidentified male: Perfect, thank you. I want to thank our panelists for presenting and thank you to all the attendees for being here. Again if you take a moment to fill out the survey after, there will be an opportunity to ask any follow-up questions and any of the questions you have already submitted will get to our panelists as well. With that, I want to thank you guys and have a great afternoon.

Unidentified female: Thank you all.