Don Workman: Those of you on the left coast, good morning to you. We wanted to cover some of the important issues that were identified, actually, in the last calendar year. For those of you who’ve seen the annual report that comes out from the Central IRB, in that report we identified factors that contributed to delays in improving multi-site studies. A number of those factors were linked to our forms. Then, at the end, there were goals for this calendar year ‘23 and the goals, many of them corresponded to those factors. I’m not sure where we are on the slides there. Can we advance to the one that has my introduction? Thank you. Next slide.

Among the factors that were identified, there were redundant questions. Again, the development of Central IRB forms occurred over more than a decade of time. So, different questions were added or changed in such a way that when I started in 2021, there were redundant questions across forms, and that led to an actually extensive administrative pre-review that was often done by our staff to create a bunch of changes to make answers and information across the application documents consistent. In the end, that administrative process, or making those changes, results in an additional cycle of review, and our anticipation is that by improving the forms, we can hopefully cut down that one cycle. There also seemed to be an excessive number of forms. Jessica is going to give you some more information about the changes that have been made, but one of the other items was missing or dated documentation. When we asked for investigator financial conflict of interest review and the study team’s CITI training--when we actually asked for the documentation, sometimes we’d get documents that had expired or were missing. Again, that’s another part of changes that we hope will increase the efficiency of our process. Then, in our continuing review process, the LSI applications each had their own continuing review report, and then there was a TISC continuing review report and it was a bit redundant. Our goal in making changes is to have a much more efficient process for the PI to compile the application for continuing review so all of the information is collapsed together in one report. Finally, we have new study teams, new investigators, coming on and at times, our processes--the complication of it--created, again, work that had to be redone. Next slide.

In our current year goals, we are again resolving the redundant questions. We are trying to move away from the need for an administrative pre-review and move right to regulatory review and remove that additional cycle. We’ve also reduced the number of forms so hopefully that will be clear to you all and have dropped the requirement for documentation of conflict of interest review and study team CITI training. This is not a change in the requirement. The requirement persists, but we’re not going to ask for the documentation coming back to the Central IRB other than a checkbox to verify that it’s been done. And then, our integrated process we think will improve continuing review, give more information to the IRB, and provide more information to the R&D committees who are approving some part of the whole study. Finally, we hope to make this a more user-friendly process so that new investigators or study team coordinators can step in and have an easier learning curve. Now, I’ll pass it on to Jessica.

Jessica Kroll: Thanks, Don. Next slide. As Don briefly mentioned, the objectives of today are really for the Central IRB to share an update on recent and upcoming changes to our forms and processes. This webinar will cover the following topics: an overview of all the changes, a description of the process changes, form changes, and what’s next. Next slide. And the next.

Why change our forms and processes? Don provided a great introduction and explanation of our goals for this year, which ties into this slide and the work that we have been doing. To add on to what was already mentioned is that many of the changes that I will be sharing today are to better align our forms with the required IRBNet wizards such as the Information Sheet and Project Cover Sheet; to improve usability and provide better instructions for our researchers; to eliminate unnecessary submission forms, which will in turn reduce inconsistencies and reduce those submission errors that often lead to that back and forth; and to focus on capturing relevant information for the Central IRB to conduct an efficient and compliant review. That leads back to the elimination of duplication of reviews and oversight between the local research office and the Central IRB. Next slide.

Process changes. The process changes that will be described in the following slides are going to take effect tomorrow on June 28th. During the transition to the new process and the new forms that I will describe later, Central IRB managers will work with study teams to be flexible and accommodating for any submissions that are in progress during this transition time. If there are any questions about a new process, please always feel free to contact the Central IRB manager that is responsible for your project or a Central IRB administrator. Next slide.

The first change is reference to principal investigator. The Central IRB is removing all references to “Study Chair” from the title “Principal Investigator/Study Chair” which we have always referred to as PI/SC. The reference going forward will now be “Principal Investigator” or PI only. The reference to “Local Site Investigator” or LSI is not going to change. Next slide.

Researcher training. The Central IRB will no longer verify human subjects research training completion dates for study personnel. The Central IRB will, however, require a checkbox attestation that training requirements have been verified locally prior to submission to the Central IRB. The important note is that study teams must continue to follow national ORD policy and requirements for completing training and know that this change is only reducing the duplication of oversight and relieving the Central IRB from reviewing training dates that are already managed locally. Next slide.

The next process change is investigator conflict of interest documentation. The Central IRB will no longer require COI documentation to be submitted for investigators unless there is a conflict of interest management plan. If there is a conflict of interest management plan, then the plan must be submitted. The Central IRB will now require a checkbox attestation that conflict of interest requirements have been verified locally prior to submission to the Central IRB. For example, new projects, this will be attested to in the Form 102 for ACOS review. Amendments will be in Form 116, and with continuing reviews, that will be documented in Form 115a or 115b. Please note that study teams must continue to follow national policy and requirements for conflict of interest. And again, this change is only reducing duplication of oversight and relieving the Central IRB from reviewing COI documentation that is already managed locally. Next slide.

Reportable events. The Central IRB Table of Reporting Requirements has been updated to reflect our current definitions and submission requirements. Additionally, a new single Reportable Events Form 124 that captures all types of reporting categories has been created. The contents of Forms 119 UAP/SAE and 129 Protocol Deviation are captured in this new form. That means the Forms 119 and 129 will be discontinued. Also to note, Reportable Events that are submitted to the Central IRB but don’t require prompt reporting and are able to be reviewed outside of a convened meeting, will have a change in their review type. Reviews are changing from what we currently document as an “expedited” review with an “acknowledgement,” will change to an “administrative” review with an “acknowledgement,” as these submissions do not qualify as an expedited review procedure. Reportable events that fall under an administrative review will continue to be reviewed by a designated voting member of the Central IRB. This change will be reflected in Review Details in the IRBNet project and will also be noticed in Central IRB Determination Letters. Next slide.

RCO Audit Reports. The Central IRB has collaborated with the Office of Research Oversight to develop a more streamlined process for submitting local RCO Audit Reports to the Central IRB. The required process of how to submit an RCO Audit Report is detailed in the new Central IRB Table of Reporting Requirements, which specifies how to submit if you are an investigator or how to submit if you are an RCO. If you are an RCO, there is a section at the end of the table with specific instructions on how to submit in addition to the investigator requirements. This new process allows for RCOs to submit audit reports with no findings or findings not required to be reported within a specified timeframe directly to the Central IRB using the new IRBNet RCO Audit workspace. Next slide.

RCO Audits with findings of Apparent Serious Continuing Noncompliance or apparent UPIRTSO must be submitted by the responsible investigator using our new Reportable Events Form 124, and follow the reporting timelines specified in the Table of Reporting Requirements. This can be done in one of two ways. One, the RCO provides the responsible investigator with the audit report, and the investigator in turn will submit the report to the Central IRB as part of a Reportable Events Package in IRBNet using the new Form 124. Alternatively, the RCO may submit findings by email to the investigator and the Central IRB using our Central IRB email. In the email, the RCO will clearly indicate that there is a finding of Apparent Serious Continuing Noncompliance or apparent UPIRTSO and inform the investigator of the prompt reporting timeframe to submit the findings as a Reportable Event Package in IRBNet directly to the Central IRB. Next slide.

The overview of form changes as we’ve wrapped up a description of our process changes. All Central IRB forms have undergone minor formatting and administrative changes. These changes include new headers, new instructions, and improved fillable formatting. The following slides will provide a brief summary of significant changes made to each of our forms, the date the form will be released for use, the date the new form must be used by, and a list of forms that are going to be discontinued. Next slide.

The Central IRB is releasing new forms in three scheduled phases. Phase 1 was the release of continuing review forms, and this release took place on June 14th. Phase 2 is the release of post approval submission forms. This release will take place tomorrow on June 28th. Lastly, is a Phase 3, which is the planned release of the remainder of Central IRB forms which are the new project submission forms. The new project submission forms will be released at a date to be determined, but likely at the end of July or early August. We will still provide an overview of the changes to these forms today so you are aware of what will be coming. Next slide.

The continuing review forms here have been updated and released on June 14 and as indicated, must be used by August 14. Significant changes include aligning the PI and LSI form sections, replaced training, credentials, and conflict of interest with a checkbox attestation; removed an option to add and remove staff, as that is managed in real time by the local facility; and lastly, protocol deviations and adverse events will no longer be reported with the continuing review form but will be reported on a separate, new log that will be an additional attachment to the continuing review package. More detailed information about the changes of the continuing review forms and process can be found on a recorded VAIRRS webinar from June 13 as well as on the Central IRB website. Next slide.

The next few slides will describe Phase 2, post-approval submission form changes that will be released tomorrow on June 28 and again, must be used by August 14. Form 130 Annual Status Report includes changes such as removing the Verification of Staff section. This form will no longer require a listing of all study personnel, nor will it allow for staff to be removed or added. Again, the reason for this change is that study personnel are managed in real time at the local facility. Providing this information to the Central IRB created a duplication of reporting for the study team. Below, the project closure forms have been updated, however, there are no significant changes here to report. Next slide.

Form 116 Amendment Request. This was revised and we added new sections for change requests as well as revised change request section to include an updated listing of documents that are required once specific changes are being made. We also replaced training, credentials, and conflict of interest with a checkbox attestation when adding key personnel. There were no significant changes to Form 127 Protocol Exception Request. We did create a new Form 131 Administrative Update. This new form will be a requirement any time there is an administrative update. The Central IRB will no longer accept a cover memo to be submitted describing the update. This new form will provide a more formal submission of LSI updates due to PI amendments, LSI site specific changes, and PI administrative updates that do not require an amendment; for example, an update to a phone number in a consent form. Next slide.

As previously mentioned, we have a new Form 124 Reportable Events. This form will capture all categories of events that may need to be reported according to the updated Table of Reporting Requirements; for example, UPIRTSO, apparent noncompliance, incarceration of a participant on a protocol that’s not approved to include prisoners, et cetera. Contents of Forms 119 and 129 are going to be captured in this new form, and therefore, those forms will be discontinued. There have been no significant changes to any of our waiver documents so that includes Form 103 Waiver of HIPAA Authorization, Form 112a Waiver of Informed Consent, or 112b Waiver of Documentation of Informed Consent. Next slide.

Form 102 Local ACOS Review will no longer be used for investigator conflict of interest documentation. This form will go back to its original intent, which is to be completed by the PI or an LSI’s local ACOS when a new project application is submitted to the Central IRB. Additionally, when there are Co-PIs from different VA facilities, each Co-PI must have each local facility ACOS complete this form. The Form 102 now allows for the ACOS to certify that all local training, credentialling, and conflict interest review has been completed prior to the new project being submitted to the Central IRB. The last form to be released tomorrow is Form 140 Central IRB Memo, which is a generic memo template that can be used when addressing the Central IRB in an IRBNet package. However, please note that the memo cannot be used in place of a required submission form. Next slide.

Now to move on to our new project forms. The PI and LSI New Project forms will be released in Phase 3, and as mentioned, it will be at a date to be determined in late July or early August. The release of these forms is pending a concurrent update to the VAIRRS IRB Information Sheet wizard. The following slides will provide a description of the planned revisions to our new project submission forms as well as new forms that will be created to better support an efficient review process. The Central IRB will inform the field prior to these changes taking place, again, in late July or early August. Next slide.

Protocol Template has been assigned a new form number which is 100. This template will be used only for projects that involve subject interactions or interventions. With that, new sections have been added to the Protocol Template to collect more comprehensive information and to refocus the protocol on multi-site aspects of the project. Additionally, the template was revised to incorporate elements of Form 108, meaning Form 108 will be discontinued. Additionally, the Protocol Template includes more detail and descriptive instructions to support writing the protocol. There will also be a Form 101, which will be another protocol template that’s specifically going to be for data/specimen-only projects. In this new form, it will contain similar updates as Form 100; however, it will not include the content regarding subject interactions or interventions pertaining to recruitment, consenting process, et cetera. Next slide.

There were no significant changes to Form 105 Request for Exemption. Form 107 Co-PI at a different VA facility is a new form that’s replacing Forms 105a and 108a. This new form can be used for exempt and non-exempt projects; however, please note that this form is only required when there is a Co-PI located at a different VA facility. Co-PIs from the same VA facility do not have to complete this form as their role will be fully captured in the Project Cover Sheet. Form 109 Coordinating Center Supplement is a new form replacing 108b, and this new form can be used for both exempt and non-exempt projects. Next slide.

The following slides provide a listing of forms that have been or will be discontinued. This again, is in an effort to reduce the collection of the same information across multiple forms which has often led to issues of inconsistent information being provided and multiple rounds of revisions being needed. However, please note the discontinuation date of some forms is to be determined based on the release date of the New Project submission forms, which will be in late July or early August. I will briefly list some of the forms that are to be discontinued and provide a description of where that information will now be captured. Here in this table, 104 No Subject Interaction LSI, this will now be captured into a single Form 104 LSI Application that will cover all LSI project types. Forms 104a, 105a, and 108a, which were all used for adding Co-PIs or Co-LSIs, are no longer required as this information will be captured in the Project Cover Sheet wizard. If applicable, the new Form 107 Co-PI at a Different Facility could also be used. As I previously mentioned, Form 108 will be discontinued, and all contents of the Form 108 will now be covered in the Protocol Template, the IRB Information Sheet wizard, the Project Cover Sheet wizard, and the ERDSP. Form 108b Coordinating Center Supplement will be changed to a new Form 109. And additional information will be captured in the information sheet. Next slide.

Content from Forms 110a and b for Vulnerable Populations will be captured in the Information Sheet and Protocol Template. Form 115c Documentation of Conflict of Interest for Continuing Review is no longer required, and that form was discontinued on June 14. The following forms in this table will be discontinued tomorrow on June 28, however, they will remain in our forms and templates library temporarily for any projects that are currently working on these forms. As previously mentioned, Forms 119 and 129 will be replaced by Form 124 Reportable Events. Form 127a Protocol Exception for COVID-19 is no longer required, and all protocol exception requests can be made using Form 127. Forms 134a and 134b Change in PI or LSI will be captured in Form 116 Amendment Request and the Project Cover Sheet. This concludes the changes to our Central IRB forms. Next slide.

I’d like to share some key takeaways from all of the information that was just provided. I know there was quite a bit of information. Some important things to consider when we move forward is that when Form 108 is going to be discontinued, project documentation is going to center around the Information Sheet wizard and the Protocol Template. The Central IRB, however, will not require any existing projects to convert a currently approved protocol to the new Protocol Template. The Project Cover Sheet wizard will be the new source documentation when key study personnel are listed or added to a project. The Project Cover Sheet is capable of identifying who is in an investigator role, their VA appointment, their 8ths, et cetera. Lastly, as just a reminder that project documents must stay up to date and always reflect what the project is currently approved for. When an approved project is submitting an amendment, all applicable documents must be updated and submitted if it’s impacted by that change. Next slide.

In how to prepare for some of these upcoming changes, first and foremost, continue to always download VA Central IRB forms directly from our IRBNet Forms and Templates library when they are needed. This is to ensure the current version is being used and submitted with a package. The Central IRB is going to continue to provide communications to the field regarding these changes that are taking place tomorrow for Phase 2 as well as the Phase 3 changes later in July or early August. These communications are going to be shared with the field through email, the VAIRRS Newsletters, and posted on our website over the next few months. Additionally, we have a lot of Central IRB Researcher guidance and instructions, and these will be updated on an ongoing basis through August and uploaded into our Forms and Template library when they become available. Another important reminder that I would like to share with everyone is to continue to use, or to begin to use if you haven’t already, the “Version Control” within IRBNet. This is to support maintenance of revision history of existing documents. This is done by using the pencil icon next to an existing document to replace it rather than uploading it as a brand-new document. And last, if there are any questions about the forms or process updates discussed today, please contact the Central IRB at our general email address. Next slide.

I think we can open it up to questions. Thank you. What form will document the annual status financial conflict of interest disclosure is completed? In one of my previous slides, I had identified where this will be able to be attested. There will be checkboxes for an attestation that it has been completed. For new projects that will be in Form 102 for the local ACOS review. For amendments, that will be in Form 116. And in continuing review, the attestation will be in Forms either 115a for the PI or 115b for the LSI.

I thought 115b was obsolete and replaced by the checkbox on the 115a. Is this correct? If this is a question in regards to the conflict of interest, that is not correct. 115A is specific to the PI and that could be a different listing of personnel, whereas the 115b is for the LSI site which again could be a different listing of personnel. Each of those forms will have a checkbox to attest that the training and conflict of interest has been reviewed and is up to date before the continuing review is submitted to the Central IRB.

How do I access the new Central IRB Table of Reporting Requirements? The one in the library is from 2015? I will be adding the new table tomorrow, June 28, and I will also be…well, I’ll be adding it to the library, but it’ll be also added to our website. The Central IRB website will have a version as well.

Do staff additions/removals need to be submitted to the VA Central IRB in real time or only submitted locally? We have updated our Form 116 Amendment, which has a description of when personnel will need to be added or removed from a project in real time with the Central IRB. I’d recommend referring to our updated Form 116 for that guidance.

Should the Project Cover Sheet updates be sent to the Central IRB? Again, if it aligns with the changes that we require according to the description in our Form 116, then you will submit the Project Cover Sheet in addition with the amendment which would be in regards to the changes in staff.

I suggest contacting the VAIRRS control group as many of your changes are linked to the Project Cover Sheet for gathering personnel information. VAIRRS is planning on two new forms to pull the PI/staff information out of the Project Cover Sheet. They were planning on releasing those form changes relatively soon. Yes, we are aware of those upcoming changes; however, we wanted to keep moving forward with what we’re changing at the Central IRB. And once these changes to the new personnel forms, the wizards that will be separate from the cover sheet, go into place, we will update our process.

What should the Central IRB do if it gets a revised submission that did not use the “pencil function”? Who should be checking this and communicating with the study site? Right now, the Central IRB isn’t requiring version control, but we are strongly recommending it as it makes organization of the documents within the package more manageable but also for the researcher and the documents within the entire project itself.

Does the pencil icon still work for forms that are uploaded, for example not created using the wizard, or will edits to information in those forms require uploading a new version of the file? I may ask Angie from the VAIRRS group to do a demo on this versioning in the near future as it seems like it’s something that many sites or researchers are not familiar with using. But ultimately, I recommend using this on documents that you upload as an attachment, not the wizard. If you have a protocol Version 1 and a few months down the road you want to update protocol Version 2, instead of adding a new attachment and uploading a second protocol document, you can use the pencil icon and upload a Version 2. And what it does is it virtually stacks the versions on top of one file within your designer view. Next question.

Annual status and continuing review are different. Are they using a CR form for submitting Annual Status Reports, or will an Annual Status Report form be used? Annual status and continuing review are different. That is correct. The process for submitting a continuing review is based on whether or not the project has an expiration date and is required to submit continuing review. If a project is required to submit an annual status report, there is a specific form to submit an annual status report, and that has a different date and a different requirement. But if there are any questions, if this is regarding your project, you can reach out to us at the Central IRB, and we can work with you on identifying which submission is required for you.

Unidentified Male: That is the last question so far. I see one was just added. We’re just going to review it and have it up in just a second.

Jessica Kroll: Okay.

Unidentified Male: It looks like that question might not be applicable to this webinar. I think Tammy \_\_\_\_\_ [00:41:11] may follow-up offline. As for now, right here is the last question.

Jessica Kroll: Great. Thank you, Parker, and thank you everyone for attending today.

Unidentified Male: Thank you to our panelists and thank you for those being here. As a reminder, if you can, just fill out that post-webinar survey. We do really appreciate that. Thank you and have a great afternoon.