Don Workman: This webinar is being offered to review some of the changes that we’ve made to the VA Central IRB’s Reliance Agreement. The Reliance Agreement is a somewhat detailed agreement between the VA Central Office IRB and the facilities who rely on its review.

I'm just going to touch on the major changes in that document with you and we’ll have an opportunity for questions and feedback from all of you.

By way of update, an email was sent last Friday morning by Lindsey Martin to our list of Central IRB liaisons, informing them of the new MOU and giving a written summary of the major changes, as well as access to the documents. We actually already have one revised MOU back and fully executed. So, thank you, I really appreciate your assistance in getting these filled out.

Today, I'm going to cover a couple of things; the timeframe and requirements for updating. I'm going to talk about the major changes to the document and modified Central IRBs SOPs. If you’re not aware of the changes that we’ve made, I’ll give you information about that, as well as a new Table of Reporting Requirements and RCO Information Sheet.

And then, we’re going to talk briefly about the process for modifying the MOU. In case some of you are new, we do seem to have fairly rapid turnaround on folks who are in the liaison roles. So, if you’re somebody who’s managing that, we’re just going to touch on how to administratively manage those changes and then, time for questions and feedback.

In terms of timeframe, we’re asking to have them endorsed and returned, if possibly, by September 1st just to have a whole batch with common ending dates and starting dates. And this is the last document that synchronizes a number of things that we’ve been doing at the Central IRB. We have updated SOPs and there will be a new updated SOP. I looked right before the webinar and it still has not gotten onto the website but if you look in the next day or two, you should see an updated SOP.

We already have an updated Table of Reporting Requirements and an Information Sheet for RCOs. And all of those include the same changes that are currently in our revised MOU.

I want to touch on a number of changes in our process since the last MOU. Many of you know that we changed the process for reviewing multisite exemptions and we currently use a PILSI model to recognize – that was much easier to recognize for R&D Committees, at least the ones that we spoke to. So, welcome your feedback on that process and how well that works or doesn’t work for your site based on what we can improve [mumbling].

There are a number of changes coming. We’ve announced a number of new forms that are currently in the IRB library and we’re waiting for the revised information sheet. At the time, we will also include a number of additional changes in our forms.

We’ve changed in our SOP and now, in the MOU, our process for verifying CITI training and annual financial conflict of interest completion. I’ll get to that in more detail in a moment.

We have a new review – a continuing review – process based on the forms that are currently posted in IRBNet and we have new RCO reporting processes for reports within the \_\_\_\_\_ [00:03:50] findings.

And I want to clarify a number of new responsibilities, primarily involving the addition of Panel 3, which I’ll talk about in a moment.

So, this SOP only applies to Panels 1 and 2, which for some of you, is a question; “What is he talking about? What is Panel 3?” So, the VA Central IRB now has three panels and Panels 1 and 2 are the ones that most of you are familiar with that review multisite research. Panels 1 and 2 are broke apart and that have been in place since 2007.

Panel 3 was just begun this year and Panel 3 is a centrally managed panel for a group of single facilities. So, it’s a single-site approval IRB and that may mean a multisite study is being approved just at that site. But this would not be Central IRB studies. Central IRB studies are approved by the Central IRB and there’s no need for a local IRB. Panel 3 functions as a local IRB for, we’re projecting, up to eight institutions. It’s a way of assisting institutions that do not have enough convened review to keep an IRB meeting frequently. So, our goal was to include up to eight facilities in that panel.

We also are recognizing a number of changes that we’ve made in our SOPs. And if you haven’t looked at the SOPs, we dramatically reduced the size and scope of the SOPs, taking out policy language in order to keep them current and to make them more easily digestible.

But a couple of changes to the SOPs. We no longer ask for documentation of investigator Financial Conflict of Interest Review or if the investigator or study team updated CITI training; but only verification that they are in compliance with national policy.

Some of you remember, actually, when I started in February of 2021, the Central IRB was usually collecting the OGE 450 ALT VA form. And we stopped that rapidly when we went into IRBNet because the IRBNet was not secure for submission for the IRB. It is secure for the current submission, the Conflict of Interest module, but that wasn’t the case with the IRB side of the house. And so, we changed that and we improvised and created several forms that could be used to document compliance.

We’re trying to further simplify that by the Central IRB not requiring the documentation; only attestation of the investigator that the requirement has been met and the MOU and the SOP both clarify that the Research Office only needs to contact the Central IRB when there’s a management plan. So, our goal is to reduce unnecessary Research Office work and reduce potential delays in IRB processing while also recognizing and keeping in place the key role we play in working together in managing financial conflicts of interest when they exist.

With regards to CITI training, CITI is something you remember back in 2000; NIH introduced a requirement for human subject protections training for investigators and key research personnel and it was late to getting the funding for research. But in most of our institutions, we then went to the IRB and asked the IRB to track that because the IRB could track that at almost like a point of sale. When somebody’s applying for the research protocol, it’s tied to the funding, there would be a way for the institution to ensure that the training had been met.

Interesting tidbit of history; the Collaborative Institutional Training Initiative, or CITI, was launched in the same year, in 2000, to address the requirement with an online training program. And members of the VA were invited to participate in the development of some of those early modules. That’s why our connection to CITI is, in part, a training program that we helped develop.

So, again, the goal is to reduce unnecessary Research Office work, getting documentation from the investigator to us, and to reduce potential delays in IRB processing.

So, I would note; this is not change in ORD policy. The IRB’s never been required to collect the documentation. We will continue to ask for attestation that the Financial Conflict of Interest and the CITI training has been updated because, again, they remain just as important. It’s just we’re not asking for the documentation itself.

Another change in our MOU is we’re no longer talking about different systems. Everything now is in VAIRRS or IRBNet. And so, all of our findings, communication between the investigator to the facility, are all done now by means of IRBNet or VAIRRS.

We publish our board documents for each package and that’s intended to provide a steady way of communicating clearly to the investigator, the RDC, as well as RCO and other facility personnel who need to have access to that information. And because we often get questions about it, our SharePoint archives do remain, and will continue to remain, for some time, for accessing documentation of Central IRB reviews prior to IRBNet implementation. So, if you need access and find, for some reason, you don’t have access to the SharePoint site you used to have access to, notify Lindsey Martin from our office and we’ll make sure that we get the permissions restored for you.

Also, want to point out the VA Central IRB will continue to provide written notifications of any findings of serious or continuing noncompliance or UPIRTSOs – Unanticipated Problems Involving Risk to Subjects or Others. And we’ll do this by email in addition to in VAIRRS to the investigator, to the medical facility director, the research compliance officer, and a courtesy copy will go to OROHR, as well as we provide it to the VACO HRPP Institutional Official, who is separately notified. And again, that’s in addition to the notification in VAIRRS itself.

Our notifications will continue to be made to liaisons when we have approved minutes. I will point out that the MOU no longer says, “Signed minutes,” it just says, “The approved minutes,” are uploaded to the SharePoint site and then, that notification will also go out when the annual report is uploaded for RDC review.

In addition, the MOU reflects a change that we made in our process for reviewing and documenting exemption determinations, including those requiring limited IRB review. Those of you who process these know that we adopted the PI/LSI model for these reviews, and that was done because it was confusing to R&D Committees to receive documentation that had another city listed on it in another state, and another state listed on it. So, again, using the PI/LSI model that is familiar to some of you made a lot of sense and we hope that that’s been a much clearer process.

I will point out, too, that it says, “PI/LSI.” One of the changes that we’ve made with the initial announcement of new forms coming out was we’re no longer referring to it as the “PISC” Because we very rarely get a study chair application, it’s usually just a PI application. So, again, trying to streamline and clarify.

Another change; the MOU now clarifies the process for RCOs to submit audit reports. And we appreciate the diligence of the RCOs in getting these reports to us. Many of you know that the RCOs were given a workspace themselves; it was developed in IRBNet. But it was only a few months ago that the VA Central IRB had access to operationally control things in that workspace.

And so, as we’ve come to understand the workspace, we are requesting that the audit note space be limited to find audit reports with no findings or findings that don’t require reporting within a specific timeframe. And we’re working with IRBNet to see if there’s some additional functionality that we can get out of that site. But at this point, we’re asking for the workspace to only include those audit reports because we don’t have a way of assigning the submission to an agenda or to a package that can be processed in a way that an audit normally can.

So, the second bullet; when RCO audits have findings of Apparent Serious or Continuing Noncompliance, or UPIRTSOs, we ask that they be either provided to the investigator who submits it as a repackage, along with the Form 124 Reportable Events Form, to the VA Central IRB. And the alternate there is if the RCOs want to submit the findings by email, they can send them to the investigator and the VA Central IRB using the VACentralIRB mailbox @VA.gov. And then, the email we request – or remind the investigator to promptly submit the package as a new package with the Annual Reportable Events Form in it.

In addition, the new MOU now clarifies the local context review, which occurs prior to a new application coming in. And this is a change to our previous process that was actually initiated with our going into IRBNet back in March of 2021, but it’s more clarified in the MOU that this is to happen before initial submission. The intention from Central Office is only to request that a feasibility review be done to ensure the project is actually capable of being done at the facility; that it’s in scope with the facility’s research mission; and that there are necessary resources to support the research; and investigators are credentialed and current.

This isn’t intended to say you need a full R&D Committee review at all. It’s just a review to ensure that it won’t get to R&D Committee, for instance, and be determined not to be consistent with the mission of the facility or out of scope in some other way.

The local context review also includes any site-specific SOPs or state laws that may be relevant to the research.

And then, finally, the MOU has been modified to clarify the role of VAIRRS throughout and its documentation, and we’ve actually written a document for the first time to presume electronic signatures of those two wet signatures.

So, a couple of other changes that are combined with a reviewed MOU; our SOPs have been combined into a single document. And those of you who haven’t seen it, Version 10.0 – again, an hour ago, Version 10.1 was still posted on the website and that was dated March 30th. Version 10.2 will be updated soon, and that’s dated July 20th, which is the same version date on the MOU.

I’ve given you the URL and the slides – I believe a version of the slides was sent before. Another version will be posted to the website once the webinar is posted.

But also, kind of a Table of Reporting Requirements that’s updated; it goes through the various things that need prompt reporting and the timeframes from 1058.01 for making those reports, as well as the proper format, including what forms might need to be submitted along with those reports. And then, we have an information sheet for RCOs that has also been updated on the Central IRB website.

So, I'm going to talk briefly about how to process these documents and, hopefully, this is helpful if you haven’t done this before. The liaisons have been given an email with the SharePoint site, which is hyperlinked here, and are able to go in and get the version of the MOU in a Word file.

There are two versions; one is with the NPC and one is without the NPC. So, if you’re a facility that does not have the NPC attached to it, then, obviously, you would collect the one – or you’d use the document without an NPC.

And then, only the appointed site liaisons have permission to access the folder. So, if you’re a liaison and you don’t have access; again, please reach out to let her know and she can add you to the liaison list to make sure that you have permission.

The modification that you’ll need to make is to add the site-specific information to the Word file. So, for instance, the name of your local facility and the name of the NPC need to be added. In the document the way it’s sent out, you’ll see we have, in quotes, you “Change the name of the local Veteran Affairs facility” to the name of your medical center or healthcare system, whatever name is on your FWA. And then, if you use the “Find and Replace” feature, which you can get with Ctrl-H; again, that should be a very fairly simple process and the change is made throughout the document.

So, once you’ve modified the Word file so that it’s in final version, then, you can use the option to “Save as Adobe PDF File.” This then saves the file to your computer wherever you’re saving it as an Adobe PDF. If you open it, then, with Adobe Acrobat or Adobe Acrobat Pro, then, you’ll be able to use the – enable all the features and then, go to the Tools menu and select “Prepare Form” and “Start.”

And once you do that, you’ll get what you see at the bottom of the screen there. The electronic signature of the local facility director, for instance, is filled in and ready for the local facility director to sign.

I would point out before you do that, you also want to change the name of the local VA facility director, the name of the local VA facility, and the local VA facility address. You change all of those when you’re still in the Word document; that’s the easiest. Obviously, you can also change it in Adobe Acrobat but it’s probably simplest just to change that from the beginning.

And then, once you have the signatures of the facility director and the NPC director, if applicable, then, return the file to the VA Central IRB Office by email, and there’s Lindsey Martin’s email address. Lindsey will verify that the signatory officials are consistent with the FWAs and assign an expiration date in our SharePoint site for our tracking. And then, the file will be forwarded to the Central Office HPA, which is me, and I’ll sign the document and return it. It’ll go back to you and to ORO by email.

So, again, if you have questions about the processing or any step along this process, don’t hesitate to reach out to Lindsey Martin or myself.

And now, the presentation’s over. Ready for questions or feedback from the audience. [Pause]

So, our director’s on – is this the first one? There we go. Well, I guess that’s the first one. Our director’s on detail to another VA. Should we have our acting director sign off or wait until our director returns, which may be past September 1st?

If your director’s able to do the signature before the 1st, that’s great. We usually don’t want the acting director; we really want the signatory official for this who should be signing off. If you’re not able to do that until past September 1st, that’s fine, as well. September 1st isn’t a hard and fast deadline; it was a target.

So, yes, if the acting director signed, then, we would return it to you to re-sign. Next slide?

Please define the requirement for a local context review. So, this has been left fairly open, and the reason is because you all run your shops differently. Central Office is attempting to do what we used to do during a fifteen-day waiting period after approval of the PIFC application. And in IRBNet, instead, because we could manage the review at the beginning, it would allow us to go right from approval to PI application to having LSI applications come in.

So, our request is that this include a Feasibility Review. So, for instance, if the study requires an MRI machine, do you have an MRI machine available? If the study requires staff that you don’t have in your facility, then, obviously, it’s not a study that your facility can do. So, it’s really to avoid things coming to the Central IRB that then, when they go to R&D Committee, would be disapproved because they’re either not feasible, they’re not within scope, or some other issue.

So, that’s really what we expect. We also ask that you look at local context requirements. There are sometimes SOPs at facilities that the Central IRB needs to know about so that we can adapt to those requirements, or state laws that we need to be familiar with.

Is there a Central IRB form to record local context review? No, no form at all. Our gatekeepers are able to look into the system and know that it’s gone through your local Research Office. It doesn’t mean that your R&D Committee has to do a review of the project before it comes to Central IRB; not at all. That’s a review that is expected after IRB review, but that the Research Office takes a look at it and says, “Yes, this is feasible and within scope for our facility.” Next slide?

Regarding the review to ensure a project is within scope of the facility’s mission and it’s feasible, is there any suggestion how this is done, by whom, and the documentation? Okay, similar question. Again, we’ve left that open to be the Research Office. So, whether that’s an ACOS review or an IRB coordinator review or an R&D Committee coordinator review really is up to your local procedures. This is because, in part, when we began to implement IRBNet, it became immediately apparent that the facilities had different ways of operating and managing these kinds of things.

But this is intended to be the replacement of the review that was done, again, in the fifteen-day window between P&I approval and the LSI applications coming in.

So, this sounds like a partial R&D Committee review. Yes, the idea is it could be somebody from the R&D Committee or it could be, again, the administrators who run the office. Again, it’s up to your facility how you do that. We’ve tried not to impose much of a requirement on that or much detail. Next slide?

The slides that were sent out today did not include all sides. Yes, the full set of slides will be posted on the website, at least, when the webinar is over. And if Parker wants to correct me, he can open his mic and let you know if it’s going to be sent out by email. But I do know it’ll be posted on the website.

Parker Cunneen: That’s correct. It won’t be sent out again via email but you’ll find the full slide deck on the webinar archive page.

Don Workman: Great, thank you. Next slide?

Is there a July 20th update to the SOP? I don’t see it on the site yet. That’s correct. I mentioned that right before logging on, it had not been updated yet. But it should be coming; it just is when the webmaster has a chance to update the file on the website.

So, I’m sorry it wasn’t done before the webinar but, again, if you look for that soon, it’ll be updated with the July 20th date. Next slide?

Please clarify whether local review is required prior to submission to VA Central IRB, which is opposite the normal procedures of the local IRB and current procedures.

So, because we are one of your IRBs of record but we are not the local IRB, we can’t take into account all 108 facility SOPs, different processes that you may have. And so, we do ask for that to be done prior to coming to the Central IRB. But this is nothing new, this is nothing different. We’ve been requiring that since March of April of 2021.

Again, it does raise questions at times because sometimes people don’t know that it’s already being done. But it is something that’s done routinely before – and this is only before – a new submission comes to us. Once a new submission has come, we don’t ask for the local Research Office to review the submissions. It’s only that first time, again, to make sure that it’s consistent with what your facility wants to do. Next slide?

Clarifying the initial question on interim directors, we do not know when the assigned director will return. Again, unless the person is – absolutely will not review and sign the document by email, if that’s the case, then, let us know. Have the interim director sign it and we’ll have it updated when your assigned director comes back. But again, a minor delay after September 1st isn’t a big issue. That would be fine.

Lindsey Martin: Hey, Don, this is Lindsey. May I interrupt?

Don Workman: Yes.

Lindsey Martin: According to OHRP, I believe if there’s an interim or an acting director for over ninety days, the FWA should be updated and then, that would trigger what would’ve been an MOU amendment. But now, the new MOU can be submitted with the interim or acting director’s signature. And then, once the permanent director is appointed, you would update the MOU via an amendment once the FWA is changed.

Don Workman: Thanks, appreciate that. So, again, in trying to take a parsimonious approach, if the interim is going to be a prolonged period of time, feel free to contact Lindsey again if you have questions or our friends in the ORO Office who also manage FWAs and we’ll get that worked out. Next question?

Parker Cunneen: That is the last one we have for now.

Don Workman: Okay. Any other comments from the panelists? If not, I appreciate people attending. I appreciate you sending us questions or feedback and look forward to the next webinar. Thank you.