Deborah Eddy: If you are on the west coast, good morning. As Rob said I am Deborah Eddy, I work on the VINCI Compliance Team as the Audit Program Manager. Today what I would like to cover is the role of our team. What is the difference between operations and research studies and why that is important? The HIPPA rule including what is a patient identifier; what are deidentified data; what are aggregated data? Some of the common acronyms for sensitive data such as PII and PHI. How to use the VINCI file transfer utility and wrapping up with some common examples of pitfalls and risky behavior that we might see in this territory. Rob is going to start us off with a few poll questions so that I can better understand who is listening in today.

Moderator: Okay and that first poll is open. The question being – what is your primary role? Answer options being: principal investigator; study coordinator or admin support; statistician or programmer; other support; I work on operation studies only; and none of the above. Debbie your audience is sending in their answers quite rapidly. Let me see…things are starting to slow down now so we will give people just a few more seconds. I am going to go ahead and close this poll, one moment and share out the results. You see that 7% answered: A - principal investigator; only 14% answered B - study coordinator, admin support; 30% answered statistician or programmer, that was your largest number, Debbie; 11% answered other support and only 2% answered E - I work in operations only; then there is 12% who answered none of the above. Back to you.

Deborah Eddy: Thank you so much everyone for answering that, it really helps me target this material to our audience and it will also help me going forward on knowing how to best address the different areas that we are going to be talking about today. We do have one more quick poll for you.

Moderator: Give me one second while I open that poll up. That poll is open the question being – Debbie could you go to the next slide?

Deborah Eddy: Of course.

Moderator: What is your experience level with VINCI? Answer options being: I have no or minimal experience with the VINCI workspace; I have been a VINCI user for one to three years; I have been a VINCI user for four or more years. This one is a little bit simpler so it should probably be even quicker. At this time a full 72% of your audience has finished providing their answers, there is only a very small percentage who are in progress. That number is just about at zero so I am going to go ahead and close the poll and share out the results and read them off to you. For the question – what is your experience level with VINCI – 42% say they have no or minimal experience with the VINCI workspace; 22% about half that number say that they have been a VINCI user for one to three years; and a small percentage 15% say that they have been a VINCI user for four or more years.

Deborah Eddy: Great thanks everyone. I am hoping that everyone despite your level of experience will gain some useful information. I have tried to make this kind of a practical guide for staying in compliance when you are a VINCI user as opposed to just repeating some of the training you have gotten through TMS on the Protection of Data or all the various manuals and handbooks that are out there. I will keep in mind that we have a lot of new users today and I will go ahead and get started with the material.

What does the Compliance Team do? We do a lot more than just trying to identify people who are not in compliance. Our main role is to provide education and any other support that you need to understand the various regulations and follow them when you are trying to create or participate in either a research or an operations study. As I mentioned there are so many trainings and rules and regulations out there that let us help you stay in compliance by interpreting those for you. We do however, if you download a file out of VINCI, we will review the file and make sure that the data steward has given your study permission to do so.

I am not going to spend a lot of time on what the difference is between research and operations. It is important to know the difference and I will explain why in a bit, but here are some really good resources that you can go to for that information. There is a really good cyberseminar that Linda Coke of VIReC gave this past November that I highly recommend. I have the link there and Rob will make these slides available sometime after the cyberseminar so you will have those links there without having to try to jot them down at this time.

There is also a site called the VHA Data Portal, very valuable site with all kinds of information in doing research or operation study. I go out there regularly myself to stay on top of things. One nice feature that will be helpful to you is there is a link to a research versus operations decision tool that you would probably find very useful.

Briefly with operation studies that are often called Quality Improvement Studies or something along those lines, there is a whole different process for obtaining the data that you need for your study. There is a link that I am providing here, that will send you to the Healthcare Operations Request Process. If that link is not working for you, let me know and I will be happy to provide you with that link. Whereas the Operations Request Process will describe how you will use what is called the ePass tool and the Base Camp site to request your data and add users to the project that you will be working on. Although many Operations Program Managers will allow you to download data from VINCI to your local server, not all of them do so before you move any data out of VINCI to your local server, please check with your program manager to see if that is allowed. As I said the majority will say it is okay, but there are a few who will not allow you to do that.

Research studies that will comprise the bulk of our discussion today, generally fall under three categories: Prep to Research Studies; IRB Studies and IRB Exempt Studies. The purpose of a Prep to Research Study is to obtain access to the data that is available in VINCI, give you a chance to look at it to decide, do I want to go ahead and fully develop a protocol to submit to my IRB and maybe to prepare a grant submission or something along those lines. In these cases, we allow you to look at the data for a short period of time and if you do decide to proceed to the next step, which would be okay I am going to go ahead and provide my research protocol to my local Institutional Review Board, and ask for their approval to proceed with the study, then at that point, we would then call it an IRB study. Now more recently because of changes to the Common Rule, you may present your research protocol to your local IRB and they may say - well the chances of any harm coming to a patient whose data you are using is so small you do not even need to get our permission to proceed. At that point they will give you a letter stating that fact, and the study would then be identified as an IRB Exempt Study.

Now it does not matter which of these categories your research falls into, but the process whereby you would be asking for the data, is a tool called the DART System which is Data Access Request Tracker. We will look at that a little bit later, but in that tool, you will be asking your data steward and in most cases that is the National Data Systems Office, but you will be specifying these are the data I need and this is where I want to store it. As a VINCI user you will want to be storing it on VINCI but you may decide that for your purposes, for your study you may also need to keep a copy of that locally. In fact, you may even want, you have it locally you may need to share it with an external entity. Once your DART application is approved, then what happens next, is VINCI systems admin team will create a project folder for you in the VINCI workspace. That is the location where your team, who you have identified in DART as who is on your study team, will be keeping any kind of documentation and data that will be shared with the team. A data manager in VINCI will also be assigned who will actually be helping you acquire those data and giving you views to that data.

When your DART application is approved an email will also go out to whoever has been identified in DART as a contact and that would usually include the PI and any other designated study team members, maybe a study coordinator or someone like that and it will let you know the study has been approved in DART and it will give you the name of your data manager and also give you a link to what is called Correspondence Site. That will be the avenue you will exchange information with your data manager. It will keep it at a nice secure location, all in one place rather than trying to keep track of emails going back and forth and phone calls and that type of approach.

I will mention this again later, this is one reason it is super important when you are doing VA business to use your VA.gov email because otherwise you could miss out on important notifications such as this. Now keep in mind when you are working with research projects, and I will mention this a few times because it is so important, when you need to download data out of VINCI you can only do it with the express approval of the data steward and the mechanism for that is the DART application. An exception to that is if your study is a Prep to Research Study you are never allowed to download data for those types of studies. Always work with your VINCI data manager using that correspondence site, once you have approval for the data and they will give you views to the data.

Now many of you may have been working on both research and operations studies and at this point it is really important to remember, okay when I am requesting data from a research study through the DART application, I have to get my data using those rules and regulations by going through my data manager and my data manager will provide me with the data as opposed to well with my operations access I can look at these data myself for my research study and that is forbidden. That would be considered a serious violation of the operation and research permissions you have been given. It is important to remember the data managers are very responsive and please do not try to cut corners by using your operations access to pull those data yourself.

Now, when you go through the DART system and if you decide you need to download patient level data for your study, generally you would not need to specify in your DART application that you are also going to be downloading statistical output in aggregated data. You can always describe that in your application but you would not necessarily need to request it of the data steward. However, there is some really important caveats before you download anything from VINCI, please look it over even if it is just a quick overview. If you have run a statistical program, please do not assume that your output does not contain patient level data and just go ahead and download it. One reason is depending upon the program that you are using, you may have selected an option inadvertently that will include your complete dataset in your output file. Or even if you have not done that, you may be displaying minimum and maximum values of certain fields and that may actually include patient data like a patient ICN or even a social. Please look over those files before you download and make sure that none of those types of data are in your file before you download it.

Also, if you have created aggregated data table whether manually or as output from a program, please look that over as well before you download it because there a few considerations. One is aggregated data, this might be obvious but it might not be for everybody, aggregated data must include data for multiple patients. You cannot say patient one and here are aggregated results of some type for that one patient and here is patient two and here are aggregated results for that second patient. Aggregated data has to be for multiple patients combined.

Also, if you think about it, if you have an aggregated data table, and you have a very low number in one of the cells for example, one, well that is not really aggregated anymore you are pretty much identifying one patient. How do we determine how low your count can be to be considered sufficiently aggregated to be considered deidentified? The National Data Systems Office who is probably most of your studies data steward, has provided a document for us that provides thresholds and you can look at this document when you are trying to determine whether or not your data are sufficiently deidentified. If you have a very broad category that you are counting in your cell for example, and there are no HIPPA identifiers in it, I need a count of all patients seen in all VA hospitals in 2003. Your cell counts may be as low as three. If you narrow your criteria a bit, and you may include one or more HIPPA identifiers, as long as you are not including any local information, locality information, your counts can be as low as 11. For example, one HIPPA identifier is patient’s older than 89 years old because they are a protected group. If you have a had count of patients aged 90 and up seen in any VA hospital in 2003, your count can be as low as 11. As you narrow your criteria again, for example if you start including locality information as an example, I have a count of patients aged 90 and up who live in Broward County, your count cannot be lower than 21. If you are going to be downloading any kind of aggregated data, please keep these thresholds in mind. If you are not quite sure after you look at this whether or not your counts are sufficiently high, feel free to just get in touch with the Compliance Team and we would be happy to go through that with you. To get ahold of the Compliance Team for this or any other questions or issues, you can just drop and email to VINCI@va.gov and then I would recommend in the subject line you just put something to the effect of – question for the Compliance Team and the it will shoot straight over to us and we always try to get back to you either the same day or the next day. Rob, the rest of my screens are blank, can you help me with that?

Moderator: Goodness gracious, they appear blank to me as well. Do you have a copy on your computer Debbie?

Deborah Eddy: I do.

Moderator: Okay.

Deborah Eddy: Can I go ahead and share that?

Moderator: I think it is probably best, I do not know what happened at my end.

Deborah Eddy: Okay let me go ahead and do that, it is always good to have a Plan B. Okay here we go.

Moderator: I am going to queue up the Jeopardy music while you do that.

Deborah Eddy: I was going to say the same thing. Okay now how should I best…when I pull up my PowerPoint do I hit the share button there or how do I share that within the WebEx.

Moderator: In WebEx there is along the bottom next to mute, you can share there or across the top there is File/Edit/Share. Which one are you choosing?

Deborah Eddy: Okay let me pull that back up, this is a new skill for me.

Moderator: This is in WebEx.

Deborah Eddy: Okay I have my WebEx up and I am going to…guide me through that again, I am sorry.

Moderator: Either along the bottom where it says Mute next to Mute there is a Share button or across the top File/Edit/Share. Just tell me which one you are using.

Deborah Eddy: Okay so I picked Share.

Moderator: Which one? On the bottom or the top?

Deborah Eddy: At the bottom.

Moderator: Okay.

Deborah Eddy: Then I have one that is called Microsoft PowerPoint? Do I go ahead and pick that one?

Moderator: Yeah, I think that will be what you have open on your desk.

Deborah Eddy: Fingers crossed everyone. Okay we got it, let me go ahead and…

Moderator: Put that in slideshow mode.

Deborah Eddy: Okay. Can you see my slides?

Moderator: We can but you need to put it in slideshow mode. File/Home/Insert blah, blah, blah, slideshow.

Deborah Eddy: Okay.

Moderator: All I see is gray screen at this time I am not sure if I need to change the display settings in slideshow mode of PowerPoint. Just swap, do you have two monitors.

Deborah Eddy: Okay no I just have the one. Okay let me go ahead and…

Moderator: Maybe it would be best to take it out of slideshow mode and just move forward like that.

Deborah Eddy: Are you still seeing a gray screen?

Moderator: No, I see the slide and the thumbnail views on the side, in edit mode.

Deborah Eddy: Okay.

Moderator: It is usable.

Deborah Eddy: Let’s do that folks, sorry for the delay, I obviously need a little more training on WebEx here. Okay so I was just finishing up our definition of aggregated data and again if you have any questions on how to apply this to your dataset feel free to drop me a line and I will be glad to go through that.

When we talk about patient identifiers, you always hear about sensitive patient data which is often abbreviated as SI and there are so many acronyms out there that are in use. But the ones that we mainly use are PII, personally identifying information and PHI protected health information. There is a difference and it is important to know the difference because a lot of people just use PHI to talk about any kind of sensitive data and PII would have identifiers such as name, socials, addresses, date of birth, but not necessarily any health information. Whereas PHI adds that layer of health information such as lab results or appointment information. Now, generally when you are using VINCI data there is a lot of overlap here. Your dataset will most likely include both types of identifiers.

I would like to talk a little bit about the deidentified data. We do get questions frequently about – does VINCI provide deidentified data and we do not. If you would like to know whether your datasets are deidentified here a few good resources for you. The HIPPA rule which I am sure most people are familiar with and the VHA Directive 1605.01 go into great detail about how to determine if your dataset is deidentified. I will be providing later on links to those documents so you do not need to try to look those up on your own. I really like the VHA Directive that I have mentioned here because what VHA has done is they have consolidated the various policies out there including HIPPA and VA statutes and such that have to do with deidentification of data put them in one place for you to look at.

Now, both documents then, the HIPPA Rule and the VHA Directive that I have mentioned consider data to be sufficiently deidentified if one of two methods are used. The Safe Harbor Method and the Expert Determination Method you only either have to use one or the other. The Safe Harbor Methods is one that you are probably more familiar with. HIPPA has outlined 18 elements they consider to be patient identifiers. If you look at those identifiers and apply them to your dataset, if your dataset includes none of those identifiers you can consider it sufficiently deidentified. That is the most common method and the one that I recommend that you use. There is another option called the Expert Determination Method and what that involves and this is described in detail in those documents above, but what you would need to do is locate someone who has been sufficiently vetted, they would need to be for example a biostatistician with at least a Master’s Degree would look at your dataset and make a determination that because of the data in your dataset it would be extremely unlikely that someone could reidentify a patient from that information. At that point they would document that fact and it would go to the PI to be included in the study documentation. In either situation, feel free to get in touch with us if we can help you determine whether or not your set is deidentified or not. I will also mention in here again, that if you have aggregated data, you cannot assume that it the counts are sufficiently adequate to be considered daintified, you need to use those thresholds provided by the National Data Systems Office.

I keep talking about the HIPPA rule so let’s go ahead and look at those 18 identifiers that would possibly link your dataset back to an individual patient. Some of these are well know and some of are not so well known. Of course, you patient names would be considered identifiers, also any geographic subdivision smaller than a state including your street address. Also mention geocodes here because those are becoming more used in your research data. HIPPA does allow you to report data by the first three digits of a zip code if the number of folks living in that zip code meet certain thresholds. I will not go into the details of that right now, they are spelled out below in the fine print. Also, all elements of date except for year, for dates directly related to an individual. That would mean of course the obvious birthdate, date of death, those would be considered identifiers. If you think about, we work for healthcare facilities and we are dealing with patient data you need to interpret this element to include dates related to patients such as admission dates, discharge dates, dates of diagnosis, visitation dates, any kind of dates of service would be considered identifiers here at the VA.

There is one additional criterion that you need to know about, for patients that are over 89 years old, you cannot include birthdates or the age itself if it is over 89. In those cases, you would need to roll up the data for all individuals greater than 89 years old into one category. Telephone numbers, fax numbers, email addresses, socials, medical record numbers, health plan beneficiary numbers, account numbers, certificate or license numbers, vehicle identifiers, device identifiers, URLs, IP addresses, fingerprints, voiceprints, any kind of photos including digital images. Then the last category is a catch all and that would be any other unique identifying number, characteristic or code that could be linked back to an individual.

HIPPA even says you cannot scramble names or social security numbers and say that it is sufficiently deidentified. You are probably aware that we have data available through VINCI to a field called Scrambled Social Security Number, that would be considered an identifier. Likewise, there is going to be other data out there for example the patient ICN. You will never see that mentioned in HIPPA but because of the dataset that you will be working with you need to interpret this HIPPA guide against the actual data that you will be using and kind of think about that. Again, drop me a line, drop the team a line if you are not quite sure if a particular data element in your set would be considered an identifier and we will help you with that.

I am going to talk a little bit about the VINCI file transfer utility which is the mechanism that you would use to download data out of VINCI. You can also use it to upload data to VINCI. Now why would you want to upload data to VINCI? Well, you may be involved in a study that maybe conducted a survey and you collected data on your own from your local Veteran population, but you would like to use the tools that we have on VINCI like some of the statistic tools on VINCI to analyze the data. We have a utility that will allow you to upload those data to VINCI and then use our tools to analyze the data.

Why might you want or need to download a file from VINCI? Well, you might need to download some statistical output to share with a publication or some type of a presentation but to actually download the patient level data itself, you would need to be approved by the data steward to do so using the DART system that I had mentioned. You may need to do that to send out recruitment letters or you may need to use it as a finder file. For people who are not sure what a finder file is, it is a file that has patient identifiers in it that you would download from VINCI and then there would be some file elsewhere that you would like to match those identifiers with and that would just kind of enhance your dataset. Then you would upload this other dataset using the upload tool to VINCI.

I am going to just recap here that you need to use DART before you either access data because this is how you would request the data for your study. You need to specify who is allowed to access the data, the PI and/or the study coordinator needs to make sure that this is kept up to date. You will also be documenting where your data will be stored, on VINCI or locally or both and whether or not you intend to share them outside of the VA. There is a whole DART user guide available on VINCI Central that goes into a lot of detail and I may have mentioned there are also videos and other seminars just on the topic of DART. I would like to just share two screens with you that are particularly important that you fill out correctly in DART in order to be able to download patient data. I realize I am talking kind of fast here folks, so feel free to put any questions you have in the Q&A box. Rob is there still a Q&A box?

Moderator: There sure is and we have a few questions so things are going well.

Deborah Eddy: Okay.

Moderator: Do not worry we can go over the time it is okay.

Deborah Eddy: Okay that is good because I was not particularly quick on the draw with sharing some of these screens. Alright, so there is a screen in DART called the Data Sources Screen, there is a lot more information on it than I am showing on this snippet here. But if you intend to download data from VINCI you see where that red arrow is, you will need to have a checkmark next to the VINCI box and next to the other server location box to indicate that. When you check off the other server location box, you will be prompted for information about the location of this local server. If further, after you download the file, if you need to send that file external to the VA, you would need to drop down to that last area that is on your screen there, and say – yes, I intend to share this external to the VA- at which point you would be prompted for additional information and you would be informed that you need to obtain a Data Use Agreement with this other party.

The other screen that is especially important for downloading data from VINCI is found on the documents screen in DART. One of the documents that is on that screen is called the Research Request Memo. When you fill this out, before you upload it, make sure there is a question here that I have identified with the red arrow, the question is – will the data be stored in the VINCI environment? Now if you only intend to keep it on VINCI which is the ideal most of the time, just check off that Yes box. If you intend to also download it out of VINCI, make sure you check off that Both box. If you check off the Both box, this will expand out and ask you information about the local server. There is a little redundancy in the DART application in that regard but you still need to specify it in two different places.

If you do intend to download data also use this blue box below on the Research Request Memo to state that not only these are the data you are requesting but also you intend to download and describe the patient data you will be downloading and also explain what you will be using it for, why do you need to download it for your study. I will just mention too on the DART document screen you will see a lot of other documents there including your research protocol, your IRB approval and all that but I will leave all those details to the DART training.

Now to actually do the download, you are going to go out to this site, that I have identified here as the VINCI Central Site. We have a lot of new users today on the call so I would just recommend that if you are interested in using VINCI or you would like more information about it, that you visit this site because there is a lot of good information, there are a lot of user guides for example on - how do I pull up VINCI; what is in my workspace. There is also a user guide for using DART another one, all the details about uploading and downloading files. There are also a lot of brief videos that show you for example - I have already submitted my DART I need to do an amendment; how do I do that. There will be a little video actually walking you through those steps. This is a good source of all things VINCI.

Now when you are ready to either upload or download a file, if you look at the bottom right of the screen, there is an Applications box. You will go ahead and click on that box, and then once you do you will see a list of applications that are available to you. The first thing we are going to be demonstrating today is how to upload a file. You would go ahead and click Upload Files and then you would be brought to this screen. There will be a message up here that the largest file that you can upload on your own is 2 gb in size and if you have something larger than that, you will need to email us VINCI@va.gov and ask for some assistance in uploading that file. You will also see a list, once you click on the little black arrow where it says Select Your Upload Destination, a dropdown will appear and it will list all the project drives or disc drives I should say that are available to you on VINCI. Then you are going to go ahead and click on the place where you want to deposit this file that you have created locally. In my case you see that I have access to four drives and for the purposes of today’s demo I am going to go ahead and upload something to my home drive. Everybody who gets an account on VINCI is given a home drive by default. The reason you have a home drive is to keep personal documents, maybe you have written some code on a napkin and you want to upload it to VINCI and keep it to work on a little bit more, that would be a great place to upload it to. But you can never keep your study data there, study data always needs to be kept in a project folder on one of these other drives.

Today, I am going to be demonstrating how to upload a file that I predetermined contains no patient data to my home drive. Once I select that location, I am going to see this screen, it is going to show that I selected my home drive and it is either going to either allow me to drop the file name in that I want to upload or I can click on this and actually navigate out to the correct file. In my case I want to upload file called Aggregate Data Definition which is actually exactly what we had looked at before as far as the thresholds go. I am trying to get as much off the screen for you. Okay so I have gone ahead and I have selected that file and as I said it is called Aggregate Data Definition and as soon as I drop that into the box you are going to see a progress bar down here that shows you the completion of the upload occurring. Once that is completed you are going to see a little box saying - Okay your upload is successful and then you can click okay. Now what I would recommend at this point is before you close all this down, I would go ahead and go out to VINCI and I would check to make sure that the file that I wanted to upload has been uploaded to the correct location. Once you have done that just go ahead and click - Okay. Now you also notice at this point that maybe you uploaded something you should not have, or to the wrong location, feel free to drop the Compliance Team a line and we can just work it out and get you back where you need to be on that.

Now we are going to talk a little bit about downloads but here are some cautions. Before you launch the download tool, make sure you know the exact name of the file that you want to download including all the way down to the file type – .xlsx or whatever make sure you know the complete file name that you want to download and know exactly where it is in VINCI. You will see in a little while why it is important to know that ahead of time. Also make sure that on your local system, that you are mapped to the location where you will be depositing the file and in most cases that will be your local secure server. Go ahead and check that out before you start to download a file, make sure the place you want to download it to is in your list of options.

Then lastly just to save yourself some time, if you want to download multiple files from VINCI, I would recommend that you go out to VINCI before you initiate the download, zip up all the files into one compressed file and then when you do the download, download just that zip file to the approved location and you can unzip it there. You of course are always permitted to download files one by one but if you have to download a lot that can save you some minutes.

I think I have gotten all the warnings out of the way, but we will see. I am getting ready to actually download a file, I am going to again, I am going to go out to this VINCI Central site, only this time in the applications I am going to select - Download Files. The second I click that the first thing I am going to see is a warning – see we were not done with the warnings. What this screen is telling you is at one point when you are running this utility, it is going to ask - where do you want to save this file locally. It is really, really important that at this point in running the utility you select - Save As and at that point, it will let you navigate to the correct local server. If you select - Save instead of - Save As the file is going to end up in the downloads folder of your hard drive which is probably not going to be the approved download location. Once you have read this warning, go ahead and click - Close and then that warning box will disappear and you will see this screen here. Important, read this box that says - Before you proceed because what it is saying is okay when I run this download utility, I am verifying that I am allowed to download these data. I have whatever permissions I need to obtain from the data steward or anyone else to download these data. That is why it is important and even if you use the download tool a lot, I would just recheck it every so often, it includes information about what is considered identifiable data and it will also let you know possible repercussions if you are downloading data that you do not have approval for.

Once you have read that warning, you can go ahead and if you click on this little arrow, to the left of the red arrow, the down arrow it will let you go ahead and navigate to the file you wish to download on VINCI. As before, it is going to display the project drives you have access to on VINCI. So go ahead and select the drive that you want to download the file from and then you will probably navigate through some folders and sub folders until you get to the actual file name that you want to download. In my case, I am going to download a file from my home drive so I click on that, it will list what is on my home drive, and I have gone ahead and gone all the way through what is on my home drive until I finally got to this SAS error.PNG file that I want to download. I pre-determined that there is no patient data in this file, it is just a screen shot of an error message that I got when I was trying to run SAS and so I do not have to worry about having any special permissions to download this file. Once I click on this file name that is when it initiates the download. This is why it is super important to have pre-determined the exact name of the file that you want to download because if I get to this point and I start clicking around on different file names, maybe it is this one maybe it is this one I better look at it, each time you click on that, file name you are initiating a download. That is one way that by not being prepared you could be downloading items that you are not allowed to download. I already know this is one I want to download I click on that file name and then I will get this message that we talked about earlier, - what do you want to do with this file and here is the file name that I had selected. As I mentioned before, you will want to select - Save As. Now this box here that we are looking at may look a little different depending upon what browser you are using. The browser that I used when I made this slide was Microsoft Edge. Since I am using Edge, this is what my box is going to look like, but if you are using Chrome or Explorer, it might look different but the important thing is look for that - Save As button. Then once you select - Save As you will be allowed to navigate on your local system to indicate where this is going to be deposited. Here, in Salt Lake City, my local VA drive has been assigned with the Letter “U” and so I am going to go ahead and click on that, that let’s the utility know this is where my file is going to deposited. Then once you select that you can actually if you wanted to deposit it into maybe a folder or subfolder, within that drive you can do so, but for today I am just going to be putting it right on the U: drive. Go ahead and just double check this is the name of the file that you want to download, then click the - Save button. Once I do that you are going to see a progress bar as you can see at the bottom of the screen here, and it is going to be showing you as the download is happening, it may take a little while if you have a larger file. But once it is completed what I would recommend that you do before you close the utility is go ahead out to your local server, verify that the correct file was downloaded and deposited in the correct location. Once you have done that feel free to just close the utility. Again, if at that point you realize maybe I did not download what I should have downloaded, or maybe I put it in an unapproved location, drop us a line on the Compliance Team and we will be happy to help you with that.

Now just to kind of wrap things up, I am going to be talking about some pitfalls and some risky behaviors to keep in mind as far as staying in compliance goes. These pitfalls are based on real life scenarios, things people have encountered when they have been using VINCI data, storing it, transferring it and what not. As we just looked at with the file transfer utility, if you are not super careful in some points of using the utility you may accidentally download a file you did not mean to or you may download it instead of to your VA local server maybe you accidentally put it on your hard drive. So, pay attention to how that runs, if you would like even more detail then I provided today, go out to VINCI Central, there is an entire users guide on transferring data either uploading or downloading it.

I had mentioned that when you upload data, you have to keep it in a project drive, not your home drive. The same would go once your project folder has been created by the VINCI team after your DART approval, you cannot be moving data out of that project folder into your home drive, you need to keep it in the project folder. We become aware of that especially if you do a download, we can see where the download originated from and if we see it originating from your home drive, we will be in touch as ask you to remove it from your home drive. Please keep in mind the thresholds that have been provided by the National Data Systems Office to make sure that the cell counts in your aggregated data table are sufficient. Some folks are not familiar with the HIPPA regulation that for patients who are over 89 years old the data need to be rolled up it cannot be reported individually by ages 90, 91, 92 etcetera. Keep in mind that patient identifiers would include identifiers that are unique to the VA such as patient ICN’s or maybe the SCRSSN scrambled social data element.

When you see HIPPA stipulates not to download patient level dates, keep in mind again, because we are at a healthcare faciality that would include not just the obvious dates but also visitation dates, dates of admission, discharge, diagnosis dates anything that is particular to an individual. Keep in mind that if you do have ability to download patient data that you have to be very careful if you are going to taking screenshots not to include a screenshot with that data in any kind of a presentation or Teams meeting or any other way that someone who does not have permission to view the data might do so. Again, if you are running a statistical program, please look at your output before you download it because you may have inadvertently included patient level data in that file.

You may wish to download an excel spreadsheet with patient level data, once you have been given permission to do so, but maybe you have neglected to look at every sheet included in that workbook. Please make sure you check every sheet in an excel workbook before you download it. Sometimes with newer VINCI users you have just been added to a study team and you find some code or some other file that has been provided by another team member, maybe who has been on the study longer and you decide to download it for reference, you still are responsible for reviewing that file before you download it, you cannot assume that it does not have any identifiers in it. Please remember that box on the warning screen that says - I am taking personal responsibility for this file that I am downloading.

Please remember that even if you are just wanting to send out recruitment letters or create a finder file, you still need to have permission through the DART system to do so before you download it. Do not assume that code files do not contain any identifiers because from time to time someone may actually hard code patient identifiers if they for example want to clean up a dataset. I want to remove data for certain patients, they may actually put in a social or something like that, that is not permitted. Also, you have comments that you can add along with your code, and they cannot contain any information about individual patients either.

I will lastly remind you because this is extremely important if you have access to both operations and research studies you need to go through the correct channels to access those data. If you have been approved for research study and you also have operations access, you must go through the VINCI data manager for your research data, you cannot go pull it yourself using your operations access.

Now there, what we consider best practices that we would like to make you aware of, they may be technically allowed by the VA, but because of the fact that we are doing research here you need to be particularly careful with how you share data either with Teams or emails. I am just going to go through these a little bit.

First, I had already mentioned it is really important for any official business to use your VA.gov email to another VA.gov email. That is actually a VA regulation not a VINCI regulation. It does allow if there are certain instances, like some kind of a technical problem, that does not allow you to do that, you might be allowed to do that. But I would recommend that at that point if you are talking about research study go check with your PI and just make them aware that you are doing that. It is also not a good idea to not check your VA.gov email because you could be missing important announcements from your data steward or from VINCI for any of your studies. Also, sharing patient data via email might be technically allowed if you encrypt VA.gov email to another VA.gov email, but we ask you not to do that. Once you send off patient data you have no control over it anymore, you do not know who that file may be shared with or may be stored in an unapproved location. If some reason you consider that is your only alternative, please check with your PI. Your PI is ultimately the person responsible with how the data are used and stored. At a minimum you would want to make them aware that you are planning on doing this. VA has recently declared that Microsoft Teams is a secure tool, however, we ask you not to put patient data out there. One reason is for example everybody on the Teams call may not be a member of your study listed in DART so you should not be allowed to share that data with them. Or even if everyone you invited is a member of that study team do you really know who might be on the other end of that in the meeting. Somebody could be in an office with a few other people in it. Or if you are like me, you join a Teams meeting and then days later your still able to go into the chat part of that cell that happened a few days ago, and read anything that is there and that would include any patient data that you have shared. We ask that you not do that. Again, because the PI is ultimately responsible and if that is something you intend to do, please make your PI aware of that.

Just to summarize, keep in mind that when you are granted permission for a study, it is only to be used for that one study. You cannot share data that has been approved for one research study with another research study even if they seem very similar to you. Again, you cannot use data you have obtained for an operation study for a research study. If you find with either scenario, that you would really like to be able to do one or both of those, rarely approved options, please drop us a line on the Compliance Team and we can put you in touch with the VIReC office or other people who would need to go through that rationale with you. If you are considering removing data from VINCI stop and look at what is approved in the DART application. If you do not have access to DART please check with your PI or someone else like your study coordinator for you. Again, I recommend that VHA directive it has a lot of great information about identifiable data and includes what is in the HIPPA rule. Team leaders, PI’s, study coordinators, please remind your team that they are personally responsible for only downloading data they are approved to download and that they are downloaded to the approved location. Feel free, I have tried to mention this a few times, reach out to us because we love it when people are proactive and ask us questions about staying in compliance.

Here are some resources I mentioned most of these previously. If you want to go to the horse’s mouth about the HIPPA rule, here is the Health and Human Services website where you can find that. Here is where you cand find the VHA Directive that I have been promoting. I did not specifically talk about VHA Handbook 1200.12 “Use of Data and Data Repositories in VHA Research” because it is being discontinued in the near future. Some of the material is going to be included in other existing handbooks and such. I just mentioned it here because it might be useful if you want to read a little bit about what is a Data Repository when one might want to create one. It is there as a resource still but before you would actually act on anything in the handbook, I would recommend that you just explore what is current on those topics.

As I had mentioned in VINCI Central, there are many useful guides there. Feel free to talk to your Principal Investigator or your local Information Security Officer or Privacy Officer for questions about staying in compliance with the various regulations particularly if you have permission to provide data to an external entity you may talk to your ISO or your Privacy Officer about what is a secure way for me to transfer those data. Again, any questions go ahead and send them to VINCI@va.gov, we try to very responsive and I am very happy to address your questions and I apologize that I have gone over a little bit in time. Rob, I am ready.

Moderator: Okay we have a number of questions but attendees if you have to leave at the top of the hour, please do fill out the survey questions that come up when you exit. Quick answers Debbie because we have a bunch of questions and we would like to get them recorded. You say PHI adds the extra layer of health information so PII does not include PHI but PHI can include both PHI and PII?

Deborah Eddy: That is a very good summary, thank you. I will just say yes.

Moderator: I was once told that properly deidentified data can be emailed between a persons VA email and a personal email, that is an email to yourself not to someone else. I was surprised to hear this can you please clarify.

Deborah Eddy: Sure. The answer is you are not allowed to do that. If you have access to these data on your VA.gov email, the only way that you would be allowed to provide it outside of the VA – let me give you an example. Let’s say that you work at a university and you want to send it from your VA address to your university address. You cannot do that without special permission because the university is considered an external entity and that would fall under the category of sharing data with an external entity. I would say in your particular circumstance I would be happy if you want to drop us a line to go over that with you, but generally that is forbidden.

Moderator: Thank you. When a PI puts the obtaining deidentified data from VINCI that is incorrect?

Deborah Eddy: That is incorrect, we do not provide deidentified data. You may, your project may go out to VINCI and deidentify the data yourselves, then if you have permission download that from VINCI but we would not consider that obtaining deidentified data from VINCI.

Moderator: Thank you. Is STA-3N (VA Medical Center) considered an identifier since it is potentially a geographic unit/level smaller than a state?

Deborah Eddy: That is actually an excellent question. We generally allow for that mainly because of the population of folks involved in that. If you would like me to look at your particular instance, I would be glad to do that, but generally that is allowed.

Moderator: Thank you. Do you need approval – this person had written something in about a DART request but then they amended saying, meant to say – do you need approval to download aggregated data to be used for Team discussion or presentations?

Deborah Eddy: That would be okay as long as the cell counts in the aggregated data meet those thresholds that have been provided by the National Data Systems. Since that would consider that aggregated data would then be considered completely deidentified – yes you would be able to share that in your Teams meeting. That is a great question.

Moderator: What is VINCI’s policy on downloading data that is aggregated to the station level. I guess this one is similar – either STATN or STA-6A by month and year. An example would be patient days by facility, month and year.

Deborah Eddy: I would say probably your main issue there would be the month as opposed to the station. You would generally, as long as you meet those thresholds, you could download data by station using that…you would definitely be on the safe side if you used that third category as first thresholds go because that is location data where the counts cannot be lower than 21. I think that is what you are asking – does it need to meet that – I would say definitely you would be safe there and if you are using the station code that is kind of a location issue you would probably be safe depending upon the number of individuals at that station. Because everyone’s circumstance is a little different, feel free to drop me a line, the Compliance Team VINCI@va.gov and I would be happy to look at that for you. But again, if you are doing month you would have to be careful about that too depending upon the other criteria that you are looking at.

Moderator: Thank you. The Research Request Memo asks - will the data be stored in the VINCI environment? Would the answer be yes if all of the analysis is in VINCI but the final aggregated report without identifiers is made and transferred to the study’s VA approved local folder?

Deborah Eddy: If it is just aggregated data, you can just say yes to that question, yes. It never hurts to say both and then just specify in your narrative portion of the Research Request Memo that all you are going to be doing is downloading aggregated data. You may want to select both just on the chance that you may need at some point to download patient level data, but if all you have right now is you have the - Yes box checked off you can download an aggregated data file as long as they meet those NDS thresholds.

Moderator: When you refer to potentially identifiable information in tables, if you are using entire VA data without location, if you refer to the median and IQR of age and upper limit passes 90, does that count as PII?

Deborah Eddy: It actually would. If there were a way of changing the way that that is displayed, I am not quite sure how you would be running your program there, your script there. If you could change that to 90 and up or something along those lines that would be considered not allowable. As I said every case is different, I would be happy to talk to you about one on one as well, but generally that is okay.

Moderator: If people need to talk to you one on one would they send an email to VINCI@va.gov?

Deborah Eddy: Yes, I would recommend that you do that and then the subject line say “Attention Compliance Team” or “Question for Compliance Team”. The reason that we ask you to do that rather than jut emailing me personally is just because then it goes into our tracking system and we keep track of the day you got in contact with us and the day that we replied to you.

Moderator: You did it you answered all the questions that came in.

Deborah Eddy: I talked as fast as I could.

Moderator: Thank you. Would you like to make closing comments or should I just go ahead and close?

Deborah Eddy: I would just like to reiterate I appreciate the number of people who turned up today and I again would just like to emphasize get ahold of us any time we really appreciate people who are proactive and try to help themselves and their PI out by staying in compliance by knowing there are so many rules and regulations let us help you with that.

Moderator: Thank you Deborah. Those of you who stuck around, we really want to hear from you even more than the people who left at the top of the hour. If you would please when the webpage comes up asking you, I think it is five questions there may be more now, please stick around and answer those questions because we do record them and they will make their way to VINCI and Debbie at some point. With that I will just wish everyone a good day and go ahead and close. Thank you, Debbie.

Deborah Eddy: Thank you Rob.

Moderator: Bye.

Deborah Eddy: Bye, bye.