Tiffin Ross-Shepard: And good afternoon. Everyone, and welcome to the HSR&D Just In Time, as you'll hear this a lot, JIT, Show Me The Money Cyberseminar.

I'm Tiffin Ross-Shepard, the Scientific Merit Review Board Program Manager. And I have with me today of my, a few of my HSR&D colleagues: Eric Enone, our Acting Administrative Officer; some of our Scientific Program Managers, Cathie Plouzek, Lynne Padgett, and Kevin Chaney, so you'll be hearing from all of us.

This slide is a picture of our building, a reminder of what it looks like since it's all been a while since we've been there. I hear the food trucks are gone from outside the building, too, as well as the dog park that was right next to it is no longer there. Now that your project was recommended for funding, you are about to embark on the Just In Time process.

This process puts all the legal documentation in place to start your projects. For those of you who have not, who have done this before, you know this is not a quick or a small obstacle. You'll realize that this requires a lot of attention to detail and persistence in order to get your project started.

Please keep in mind that your start date is determined after you complete JIT. We cannot provide a start date until JIT has been addressed. Next slide, please.

During this presentation, we will cover the budget process, quad charts, IRB, data collection, DSMB, clinical trials, and the Data and Safety Monitoring Board, as well as intellectual property. But before we get started with going into all of this, we'd like to know who is participating today. So we are going to pull the audience.

For our first question, please tell us your role, and what role you have. Are you a Principal Investigator, a budget or financed analyst, an administrative officer, or a project manager, coordinator, or some other support? Heidi, can you start the poll?

Heidi: And that poll is open on the right-hand side. We'll give everyone a few more moments to respond and go through the results. And it looks like things are slowing down so we're going to go ahead and close that out. And Whitney, I can't see the results right now.

Whitney: Alright, so the results are 5% said A, Principal Investigator; 3% said B, budget, financial analyst; 16% said C, administrative officer; 46% said D, a project manager, or coordinator, or other support.

Tiffin Ross-Shepard: Great, thank you, and let's move on to our next question. We would like to know the level of experience you have working on HSR&D projects' funding requirements, so please let us know if you have no experience in this, or if you're at the beginner level, a novice level, intermediate, or advanced level of

expertise? The poll can get open.

Heidi: And the poll is open, responses are coming in. Again, we'll give everyone a few more moments to respond before we close it out and go through the results. Okay, Whitney, when you close it down, I can't see the results anymore. So I'm going to have to ask Whitney if you could go through the results there?

Whitney: Eighteen percent said A, none; 30% said B, beginner, novice level; 20% said C, intermediate level; and lastly, 5% said D, advanced level.

Tiffin Ross-Shepard: Great, this is very helpful for us to know, and hopefully, for those who have experience with every level that of experience you have, hopefully, this will, you'll find this next 90 minutes helpful. Next slide, please.

JIT will open by the end of this week. Once JIT opens, the clock starts. You will have 180 days to complete all JIT documentation. And while that seems like adequate time to complete, things usually take longer than expected, and you need to start right away.

This year, there is a major push to get you through JIT as quickly as possible. You will be hearing more about this, but the JIT database will be shut down in early 2022. So if you don't get finished in the JIT window, there may be major delays piecing together the final requirements of your JIT.

Please do not wait to get started, we expect you to submit a revised budget using the JIT budget forms within ten days of JIT opening. If your project requires DSMB, we require your DAP within 45 days. Next slide.

The amount of time that each section takes is very dependent on how prepared and responsive you are. If you drag your feet with a response, the delays increase. For your IRB, you need to have your protocol in the correct format with details in place.

There are known projects that have cleared Central IRB within three days, but if you are not prepared, the process will increase. If you are not responsive, your response goes to the back of the queue. If your project requires IRB, you need to start immediately. If your project requires Central IRB, you will probably need a waiver since it takes anywhere from five to 12 months for Central IRB approval.

Even if you think the IRB approval is not needed, you still need to have, you still need to have the IRB Committee make that determination. Additionally, if you have employee surveys, you need to allow approximately eight weeks or more for approval. So really, the takeaway from this is you need to prioritize JIT activities. Now Cathie will _____ [00:07:04], will discuss budgets. Take it away, Cathie.

Cathie Plouzek: Thank you, Tiffin. So with the first, as Tiffin mentioned, the first requirement as deadline is a revised budget. And one of the first things we want you to do is the budgets that you submitted in the applications, we don't want to see those anymore.

That is a an , an application requirement but to start a project, we need a different budget. So please, do please, please do not include these colored grant sheets, we don't want to see them ever.

And again, so please only include the templates that we will provide you in JIT. Or they can also be obtained from your Scientific Program Manager. So this is the template that you will be receiving it through JIT, or your program manager. We need in our budgets, both a budget table, and a budget justification for each revision.

If we add, if you're asked to do something, we want both documents. And so in this upper right-hand corner, you'll see a, a a version date, we need that version date completed for every budget. You can put the date for that version. Please make certain that all of this top pink sheet is completed; and note that the primary site personnel are listed separately from the secondary site.

Note that these budgets are in project years, not fiscal years, and that the budgets will be prorated based on the start date once that's determined what the, your start date is. So you want to put these, this budget is, is in project year. If there's a specific item when you – that needs to be in certain, specific fiscal year once your project is started, you, you could, should discuss that with your Scientific Program Manager to make sure that that happens so that you have available when you need it.

So I'm going to go now, and and more in depth into the budget table. So in the summary table, please include for each of the sites, the city name, and state, and make certain that you include whether or not someone has clinical responsibilities in their appointment. We've, the – we expect that this revised budget is going to closely match the application budget, and it should definitely not exceed that budget.

If there are needed increases above your original budget due to changes, you need to get approval from your Scientific Program Manager. And make sure, and that you include the budget _____ [00:10:39], and make sure you include budget totals across all of the rows, and columns.

On the budget table, please include your, the degrees, and the step, grade step, and person effort. We need this information for all personnel regardless of whether they receive funds or not. We use the grade step and effort information to calculate IPA percentages on the budget.

We allow a 2% COLA allowance for personnel. But if the increases exceed

COLA for, because of step increases, you need to include that information in the, in the budget justification under their name.

If the percent effort changes over the years of the project, say, someone's effort changes between year one, and two, and three, and four, then expect to have you include in this percent effort column four levels of percent effort so that it says, maybe, 30, 30, 20, 20. So we want to have all of that information in there in _____ [00:12:10], if for changes in the table, and in the justification.

Please make certain that your named site PIs are eligible, that they have five-eighths appointment, and are in e-Promise. This, and we will provide you with the budgetary guidance, and this is a table that's at the end of the budgetary guidance.

We'd like you to review this to make sure that you are aware of some of the eligibility requirements. And but, I was saying that there are some exceptions, if there is a, if you are preparing a budget for a Career Development Award. And there are some exceptions there, which you can discuss with Rob Small.

Some budget highlights include not requesting salary for licensed medical professionals with _____ [00:13:17] clinical responsibilities. If you have questions about any of the budget guidance items, please contact your Scientific Program Manager.

You need to be clear in your identification of roles and responsibilities, particularly with physicians that might be IT. So if the position sounds like it might be an IT position, and it's not, it's not being paid by IT funds, then you should indicate that in your budget justification, that it is a non 2210 IT employee just to make it clear, so that we don't have to ask you about it.

Please, only list VA employees under personnel. Non-VA staff should be identified in the justification as non-VA, and listed under the budget table under other, or consultants, or however they are included. So in the personnel budget justification, we expect justification, something like this:

We want you to include the eighths, and we want to know the responsibilities on the project. We don't need a long biosketch on an individual, this is not for review. This is for finance, these budgets, and so they don't need to know all of the person's qualifications. We want to know their roles and responsibilities on the budget. And so that's what those should be focused on.

So within the secondary site information, always list the site PIs first, and group all the employees together from the same sites. We don't want you to, like, list all of your Co-Investigators from all the different sites and then list other people. We want, we need these grouped together by site with the site investigator first. This helps with the tallying up the budget and making sure

that the funds are appropriately allocated.

VA employees cannot be paid consultants and physicians cannot be paid as consultants if their licensed in the U.S. Consultants are limited to $500.00 per consultation, or 250,000 per year. Under equipment and supplies, please itemize.

If you are purchasing, say three recorders, say, three at $100.00 each rather than $300.00 for recorders, because that, otherwise, we're going to assume you're going to be purchasing a $300.00 recorder. And we'll want to know why you're purchasing a $300 recorder?

And if an item sounds like it's IT, please note in the justification that you've already consulted with your local IT, and confirmed the item is not IT. Please note disposition of equipment after the project is, ends in the justification. What's going to happen to it after this project ends?

Please note that funds are no longer available for general office supplies. These are provided by your medical center. If project-specific supplies are needed and not available from the medical center, please note that in the justification, and that would be acceptable.

Please note that the audio voice recorders must comply with OIT requirements. And as I mentioned, notes the just, the disposition of the equipment in the project justification. And now, I'm going to turn this over to Kevin Chaney to talk about the travel.

Kevin Chaney: Thanks, Cathie. So for any projects that look to have travel, you'll need to ensure that you have a summary of your project travel within your budget table as part of your travel requests. And you will need to include a more detailed _____ [00:18:04] in your budget justification.

In the budget justification, your breakdown travel request budget needs to include the name of the traveler, destination, purpose of the trip; costs, such as travel, lodging, per diem. And each trip should be listed separately. We allow one request per project to present final results at a research meeting, even if it is a multiple PI project. So that's an important thing to remember.

Travel for non-VA staff is not included in the budget. So if non-VA staff are required to travel, it must be rolled into their contracts. And if you, and if your project requires a large meeting, you should contact EES for guidance. Please note that travel funds are held until requested with travel details such as, again, travel, the lodging, per diem, et cetera.

For professional development, if you are affiliated with a COIN, submit your requests to your COIN Research Office. If you are not affiliated with a COIN, we allow the PI or designee to request travel, to request funds for travel in their budget. Now, back to you, Cathie.

Cathie Plouzek: Thanks, Kevin. So HSR&D manages an intramural program. And so it's expected that the VA, that VA's staff will be hired to perform the research and provide the needed expertise. So we want you to make an effort to hire VA personnel whenever possible.

We want to limit the percent IPAs so that projects, so that we fund as an intramural program. At COINs, we limit the amount of the percentage of IPAs to 30% of the budget. And at non-COIN projects, 40% unless a waiver is approved during your submission process.

Clinicians cannot be paid as IPAs unless they are not licensed in the U.S., and then they can be paid for non-clinical work. Clinical services cannot be contracted. You may contract for other services. When you include a contract, describe the services, and do not identify individuals who will provide that service because the contract is with the organization, and not an individual.

Please note that the site where the funds for the IPA of contract will be sent, not the location of where the the IPA as is listed. So we want to know, finance wants to know where to send the funds in in that site for that, for that individual. And we need to know which institution has the contract held that can disperse the funds.

This is a frequent mistake that we find in budgets, that the site is not listed correctly as the site where funds are to be sent. As I, as I mentioned, finance needs to know that an IPA is at the University of Hoboken but but this, they don't need to know that, but they need to know which site has the IPA agree, agreement with the University of Hoboken so they can send the the funds to that institution that has the contract.

If you…. Participant payments is a terminology that is important. We cannot accept terms, identifying payments as incentives or reimbursement. If a project plans to compensate non-physician employees for participation in research, the research team needs to contact their local OGC STAR. That's the Specialist Team Advising Research. And it's recommended that this be done prior to IRB submission.

Payments to physicians or VA employees for serving as research participants are not authorized unless they are participating outside of their tour, tour of duty. And compensation for participant payments should be presented in a table in the budget justification that clearly shows how the total amount was calculated.

In addition, you should note how the payment will be made to this study participants such as canteen gift cards, Visa gift cards, check, et cetera. And note in the justification that any unused participant payments must be returned to HSR&D.

If you are using the centralized transcription services available through HSR&D, that is, is fine, the, this, the use of the services is not mandatory. And we are no longer requiring a quote for CTSP in your budget.

But if you are using CTSP, you need to refer to our budget guidance because we will need to include Salt Lake City as a research site so that the funds can be transferred. And we have instructions to those both in the budget justification information that we'll be posting in in JIT for you.

If you have transcription in your project. Let's see – research _____ [00:24:33 to 00:24:40] using Salt Lake City, and it's not already a site, you're going to add it as a site, and include Dr. Zickmund as the site PI. But if Salt Lake City is already a site, you don't need to include Dr. Zickmund as a, as personnel, but please only, and list CTSP Transcription along with, in the, "Other."

So, for IT budget items, the research funds may not be used to purchase IT items. If devices such as laptops or tablets are to be used by patients only, they can be considered patient medical devices, and thus non – can be a non-IT purchase.

But if those devices are to be used by both patient and personnel, then they're considered an IT _____ [00:25:45] purchase, and must be included on, in the IT budget. And IT-approved voice recorders can be purchased with research funds.

If you are requesting IT funds, please ask your local CIO to sign off on the request, indicating the ability to provide the funds, and include this in your budget materials when you upload to JIT. Atlas software may be purchased using research funds as it's considered scientific computing.

And it should be listed under the Other Direct Costs in the budget. SAS and SPSS may be used in the VINCI platform, so they are not approved for purchase. And we'll – please see the memo from the ORD for guidance on obtaining SAS, SPSS, and Stata at the website that we have listed here.

So when requesting a revised budget, always, as I mentioned earlier, always include the version date of the submission. Also include the duration of the study in months. A revised budget always includes the budget summary table and a budget justification.

At the beginning of the budget justification, all changes in the revised budget should be listed, and when you, when appropriate changes are also listed under a specific area. For example, if you're explaining a step increase, it should be explained at the beginning of the budget, but also added into the justification under that person.

Once you've…. One of the most common misconceptions is start dates. The

start date is only determined once you complete JIT, you have to complete the regulatory documents prior to receiving funds to, and to obtaining a start date. The other misconception is that you have to start as soon as you clear JIT.

The start date is determined based on a discussion with your scientific portfolio manager who works with finance and leadership just as secure, to secure a start date. These start dates are only available at the beginning of the month. And some – we'd like you, as as Tiffin mentioned at the beginning, we need you to clear JIT before requesting a start date, and we can't always guarantee the start date that you want.

And we're really encouraging you to get JIT done as quickly as possible because with the JIT database going down, we really want you out of JIT so that you're not, there are not additional delays.

And so, we, the one thing that if you end up with a large delay, which we are hoping that you do not, we want to make sure that you understand that for projects that start October 1, the the project has to clear JIT prior to August. Because the databases are closed in September.

So a few notes from our ORD budget analysts. When you contact a budget analyst, which you need to include the project ID, and the subject, and the SPM as a cc on, on all of this, the communication. This budget does not have to have this information readily available but ensure that there's one person that is the point of contact for any budget issues that arise.

For example, in a, if there's a project where there were funding questions, and four different people communicated with the budget, and not including the "Other," and referring the issue to different things, it can cause communication. So we really would prefer that you not contact Finance directly. But if so, only one person from your group is the person that's contacting them.

So please try to decrease the confusion with Finance, we, we we really want you to be working with your Scientific Program Manager. The program, or the PIs and should be receiving a project budget monthly, and this should reduce some of the revisions once your projects get started.

So onto a poll, Whitney?

Whitney: Yes, we're going onto poll three, that poll is now open. And the question is, "When you have a question regarding your budget or JIT documents, who do you ask? The answer choices are A, administrative officer; B, colleague; C, director; D, Scientific Portfolio Manager.

And our answers are streaming in, I'm just going to let that poll run for a few more seconds before I close it out.

Alright, it seems like things have slowed down so I'm going to go ahead, and close the poll, and share the results. We have 20% said A, administrative officer; 6% said B, colleague; 3% said C, director; and 15% said D, Scientific Portfolio Manager.

Cathie Plouzek: Okay. So thanks, we really would encourage you to contact your administrative officer because they should be aware of any new policies or questions. But yeah, your other option is your Scientific Portfolio Manager because they're working with your budget, and they should have the answers for you.

So those were you, it would be your two responses that we would really encourage you to use. Colleagues may not be current on the most recent information and could be misleading. So so now, I would like to turn this over to Tiffin.

Tiffin Ross-Shepard: Great, thanks, Cathie. So you've heard about budget forms and the budget process, so now we're going to discuss the other documentation your project may need. All projects must complete as _____ [00:33:20], some JIT documentation. For all projects, we require that PIs complete and submit a PI assurance form.

That the primary and secondary site, ACOS, which is the Associate Chief of Staff, will complete an assurance form which requires IRB review or determination that IRB is needed – is not needed, and R&D Committee approval. A Quad chart that includes a Gantt chart or of tasks over the project, and budget table, and justification.

When appropriate, you also may need to complete additional documentation. The most common are, you'll see the non-Veteran waiver, union notification if surveying employees, the OASC review for national surveys. OMB exemption if interviewing, you're surveying Veterans, clinical trial registration, and DSMB plan approval. Next slide, please.

The PI assurance form attests to the PI's agreement to comply with VA policies, and reporting. And and Cathie mentioned this earlier, PIs must be registered in ePromise at their site. It must be at their current site where the product is coming from. Next slide.

The PI– the ACOS assurance form attests to the completion of the review by the R&D Committee and subcommittees, including IRB review as well as the PI's eligibility. If there are multiple PIs at the same site, both MPIs must complete the PI assurance and the ACOS must complete an assurance for each MPI. The next slide?

A VA facility is considered to be engaged in human subjects research when someone with an appointment at that facility obtains for the purposes of the

research study, one of the following. The first would be data about the subjects of the research through intervention or interaction with them; two, identifiable private information about the subjects of the research; or three, the informed consent of human subjects for the research.

If IRB oversight is not required or not applicable, then the R&D Committee approval only needs to be submitted with the ACOS form. Please upload the IRB's determination that IRB oversight is not required. Next slide?

This JIT slide is a representation of a Quad chart. All projects in JIT require a Quad chart. The most common errors we see is that the Quad, is in the quadrant four timeline. This section should not list aim one, two and three, but instead list tasks, and be similar to a condensed Gantt chart.

Again, if you have any questions about anything that you're hearing today, please ask your SPM. Now, back to Cathie.

Cathie Plouzek: Okay, thank you Tiffin. So if you're not certain what kind of IRB you're gonna need, first contact or Scientific Program Manager, and discuss your study right away. IRB takes a significant amount of time to complete, and so you need to start it now.

In fact, we encourage you to get your IRB information submitted as soon as possible so you don't, so you don't, aren't waiting until later. If you have questions about Central IRB, you can contact their office and a a local IRB is allowed if it's only one site, and all of the Co-Investigators are at that site.

So if there's more than one site that doesn't require a Central IRB, a single IRB is now used unless an exception is applied for. But how do you determine whether or not you can use that single IRB, or you'd be an exemption? So the Office of of Research and Protection and Planning, it has a flowchart to help you to determine whether or not you can use a commercial IRB, or a single IRB, and how you decide.

So we would encourage you to look at the website for the Office of Research Protections Policy and Education so that you can have some tools to assist you in making your determinations. There are some changes so in requesting an exemption from a single IRB.

They, it, it's, ORD recognizes that as mandatating the use, mandating the use of single IRB in all cases is not logical or feasible. So facilities wishing to request an exemption from the single IRB must follow the new process that became effective earlier this year. So you will need to go onto their SharePoint site and apply for an exemption.

And you, you if you have questions, you should be sending those questions about whether or not a a single IRB is appropriate or if an exemption is possible to the e-mail address of IRBrelianceandSIRBexceptions at VA dot

gov. And so, we would encourage you, and they will respond within ten days.

If you don't get a response from ten days, you may not have used the correct e-mail address or or a SharePoint. But they are very responsive. And you can also, I would also encourage you to look at some of these single IRB resources that are available on their their webinars, and handouts that they have available on their websites.

If you are going to be needing Central IRB for your project, Central IRB is now accessed through IRBNet. You go to the IRB webs, IRBNet website to register, and there's a step by step tutorial available, you, how to use the IRBNet. And it's also available at the ORPPE sites. In fact, IRBNet has a library of previous regulatory, right, recorded seminars on a variety of topics.

Some of the processes have changed from Central IRB over the past year. And so we do encourage you strongly to contact Central IRB with questions in advance of applying. Don Workman is very, very welcoming for questions, and he will try to get you to the right person, if he's not, not available.

So there are some, one, one of the changes in the submission is, is that the PI compiles the submission documents into a package and submits them to their local research administration for a review first. After the local administration reviews the package, it's then submitted to the Central IRB. And that can be done in one of two ways, which as is indicated here.

Once that has been submitted, the the Central IRB reviews the packet, and if their _____ [00:41:51] information, more information is needed, they contact the investigator for clarification. And then it continues on as further down the pathway that they have.

So how do you get a successful succeed with Central IRB? So IRB has a template that they make, can make available to you to help you with your submission. And it's really important to realize that the IRB package is not just taking your application and plopping it into the IRB.

That will also, that will create delays. You need to format this and provide the information that they need. And there's, because there's going to be a thorough review of your documents.

If if, you should contact your IRB or your Scientific Program Manager if you're having issues locating a copy of this IRB template. We're happy to pass it on to you. I, the Central IRB provided it to us so we're happy to give it to you so that it will help you give your information to IRB in the correct format.

I mean, there are specific information that they are being, requesting, such as what is noted here, Section 5.3 informed consent procedures. In in an

application you may not provide the detail that they are asking as indicated in this example on this slide.

So how do you succeed with your IRB, Central IRB? Thoroughly review of the documents prior, prior to your submission, we want, really want you to meet with your Central IRB manager and your IRB's reviewer. And when you get questions from Central IRB, you should address those immediately.

Because the longer you delay, the longer it's going to take them, and the, and the harder it is for Central IRB to back, respond. Because once you respond, you go back to the end of the queue. So if your delayed, the Central IRB has moved onto the next packet, so you need to be very responsive.

The other thing is consecutive amendments don't help your Central IRB process; it slows the reviewers down. And you want to try to limit that, that there are downstream effects. So and it, it's also hard on on your local IRB as as well when you have all of these changes. So you want to be successful first time.

If, if you have Central IRB questions, the contact information is available on this slide. If you're not able to find the information, and you need, you need, please contact Don Workman at Central IRB, and he'll assist you, or put you in contact with the IRB representative that is able to assist you.

So back to you, Tiffin.

Tiffin Ross-Shepard: Thank you, Cathie. Last cycle, we started the requirement that any study that plans on enrolling non-Veterans is required to have an approved non-Veteran waiver. Non-Veterans include employees as well as caregivers. If you're enrolling any non-Veterans, you will see this form that's on this, on the screen, uploaded into JIT.

Please complete the form, upload the completed form back into JIT, and your SPM will send it to HSR&D leadership for approval. If you already have an approved non-Veteran waiver, please just upload that signed approved waiver into JIT so your SPM is aware that you already have an approved waiver.

Again, if you have any questions about this documentation, questions can be sent to the HSR&D Scientific Review mailbox or ask your SPM. Next slide.

If your project involves data collection using surveys or interviews, you may need to, you may need to complete certain documentation. Data collection has different requirements for the number of individuals collected, the distribution of collection, and whether the collection is from Veterans or employees.

If your project meets the criteria listed on this slide, you should have union notifications uploaded into one, into JIT for you with additional information.

Next slide.

What is considered conditions of employment or working conditions with respect to the union notification? HSR&D takes a strict approach on this process, essentially requiring that union notification occur at any time a survey or interview will be delivered to any VA employee regardless of whether one deems the questions to be asking explicitly about conditions of employment or not.

This is due to the fact that in many cases one could argue that asking about one's decision making process or their thoughts about the implementation of an intervention could be related, or linked to their stress level, or opinion about the job itself, which technically then falls under its, quote, working conditions, or the conditions in which one works in. There are several levels of union notification listed, union notification listed on this slide with the approval steps. The next slide?

For for National Union Notification, the instructions are listed on this slide. Please provide all of the required information in a single PDF document at least eight weeks in advance of your proposed start date for the data collection. This process doesn't normally take eight weeks, it can take anywhere between four to eight weeks.

So just to be careful, playing on the longer side of that. Note that the unions are very prescriptive about the placement and language of voluntary, anonymous, and confidential. The next slide?

Organizational Assessment Sub-Committee, OASC review, is required for all research and operations surveys that involve VA employees, and that meet at least one of the following two criteria: Either administered to 10,000 or more VA employees or administered to VA employees across 20 or more sites. The next slide?

The instructions for submitting an OASC review request are listed on this slide along with the contact e-mails if you have any questions. And again, you'll get copies of this presentation. I'll turn it over to Lynne now, who's going to discuss OMB exemption?

Lynne Padgett: Great, thanks, Tiffin. Alright, we're going to talk about OMB review and reproval – approval, not reproval, or exemption from OMB review. And this is required prior to conducting surveys or interviews for all projects involving data collection from, and this is the important part, more than nine individuals who are not VA employees.

The OMB exception brief needs to explain how this data collection that you, the investigators are doing, benefits clinical care. How the survey is not duplicative of the other data collection efforts, the focus is on the data collection effort. And this document is pretty prescribed in terms of what it

asks for.

Being a recent SPM, who has just gone through the training on this, I would like to also insert two points. As these documents are put together, this is not the time to cut and paste from the background of the proposal.

This is not a scientific justification for the contribution of the research at large, but rather focus on exactly these data collection benefits, and how the survey is not duplicative. So think think about the data collection process and measure burden that's included.

So the OMB brief is provided in JIT. HSR&D has an internal process for approval, and we may request additional information from you. However, the PI does not receive any specific acknowledgement or documentation other than a notation of approval as part of the JIT process. Let's go to the next slide.

This is an example of the OMB, that's really hard to say, exemption brief. So a study has to meet and one of the criteria listed on this slide to be exempt from OMB review. So familiarize yourself with the wording that exempts your study from OMB review.

Note the timing of when the survey and interview is administered; for example, don't request exemption for a quote, clinical examination, which you'll see is the second bullet point down – unless the survey or interview is administered as part of the clinical exam. If the clinical exam occurs, and then you administer your survey, that is not part of the examination. It may impact it, but it's not part of it. So I'm going to toss the ball back to Tiffin.

Tiffin Ross-Shepard: Thanks, Lynne. Just a little bit about clinical trial registration, a clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.

All clinical trials are registered with Clinicaltrials dot gov. It is very important, please do not register your clinic – your trial until your SPM tells you to do so. Registration has to be done with ART.. If you register early, it will impact your reporting.

Now, I'll turn it over to Eric to discuss DSMB. We're not hearing you, Eric

Heidi: Eric, you are muted. At the bottom of the screen, you just need to click on the unmute button right there, perfect.

Eric Enone: Okay, you have _____ [00:53:34] me, Kevin.

Tiffin Ross-Shepard: Whoops?

Eric Enone: Can you hear me now?

Heidi: Yes, we can.

Tiffin Ross-Shepard: Yes, we can.

Unidentified Female: Yes.

Eric Enone: You can hear me?

Heidi: Yes, we can.

Eric Enone: Can you guys hear me now?

Heidi: Yes, Eric, we can hear you. Go ahead.

Eric Enone: Okay I I apologize. Thank you, Tiffin, again. Data and Safety Monitoring Board provides ongoing evaluation of studies' progress, including patient including patient accrual and retention, monitoring of adverse events, and the adequacy and efficiency of analysis plan to discern outcomes that might require a study modification, or result in early cessation of the study due to its benefits or harms.

DSMB reports may be required mid-year or annual. DSMB reports are submitted through ART website. Failure to comply with the DSMB requirements may affect future funding. Next slide.

Example of studies requiring DSMB oversight: clinical trials that, number one, intend to provide definitive information about effectiveness and, or safety of a medical or by behavioral intervention, evaluate the mortality, and another major endpoint such that impurity of treatment on past safety as well as effectiveness implications.

Involve diseases with high mortality or morbidity, involving higher risks, and for large multisite for clinical trials.

Studies in which prior data suggestions, studies in which prior data suggests that the intervention being studied has the potential to induce potential unacceptable toxicity, phase 2, phase – I'm sorry, phase 3 studies with the exception of low-risk behavioral and nutritional studies, that it includes low-risk, refers to trials that list subjects expected to experience only minor side effects. And interim analyses are not crucial for the protection of the subjects.

Also included is high-risk phase 2 studies, that includes trials of interventions associated with a substantial side effects of subjects. For example, side effects that could result in serious morbidity, or death, or are irreversible, trials of diseases associated with high mortality, or morbidity, and trials of highly experimental therapies such as gene therapy

DSMB, not the PI, will determine if oversight is required. Oversight may not be required in the following scenarios: One, a multicenter IRB's phase 1 clinical trial with clear and objective criteria for _____ [00:56:57] dose escalation, if unacceptable side effects are observed.

Two, clinical trials that are expected to accrue too quickly to allow for DSMB to be constituted, and complete data, and safety monitoring. Three, single center open label phase 1 and phase 2 clinical trials, provided the local PI has access to all data, and there's an independent monitor to evaluate adverse events, and make recommendations. Next slide.

The instructions for submitting D, A, P, we go by DAP, are listed on this slide. Please note that the DAP is due 45 days from JIT opening. Now Kevin will discuss the pre-funding modifications.

Kevin Chaney: Thanks, Eric. And I am noting on my slide, here on the presentation that we're still on slide 55.

Tiffin Ross-Shepard: Correct.

Kevin Chaney: And I want to ensure that we're able to have the correct slide up with the notes and comments for that slide. Is it possible to get to slide 58?

Cathie Plouzek: Can you hear me? This is Cathie.

Kevin Chaney: Yes.

Cathie Plouzek: Yeah, my computer froze. So can someone else move the slides, please?

Tiffin Ross-Shepard: Heidi, can you get –? This is Tiffin. Can you give me control and I can do it?

Heidi: Okay.

Tiffin Ross-Shepard: Thank you, whoops, whoops.

Kevin Chaney: Whoop, go back one.

Tiffin Ross-Shepard: There you go.

Kevin Chaney: There we go.

Tiffin Ross-Shepard: _____ [00:58:52].

Kevin Chaney: Alright, thanks, Tiffin. So during the funding process, a lot of things can happen. So Central IRB might come back and require a change in sites, or personnel, or methods. People move, again, so a lot of things can happen with changes in your project prior to funding. And if some of these things do

happen, you'll need to complete a pre-funding project modification.

In order to do so, you can contact your SPM regarding why are these changes needed, and also providing documentation that needs to be completed for additional information which will come from your SPM. Next slide.

Okay, so this is our final poll, which is on intellectual property and who must disclose intellectual property to the VA. And and I think the poll is up. And so we have, A, salary, salaried employees; B, IPAs; C, WOCs, appointees with research responsibility, responsibilities; or D, dual appointment personnel; or even E, all of the above.

Whitney: Alright, that poll is now open and running. Our answers are coming in so we'll just give that a few more seconds before I close it out. Alright, it seems like it's slowed down. I'm gonna go ahead and close the poll and share the results.

We have 2% said A, salary employees; 2% said B, IPA; and then 0% for C, WOC appointees; and 0% for D, dual appointment personnel.

Kevin Chaney: And it looks like those that were able to answer the 45%, all of the above, that is correct. We all have a responsibility to report intellectual property. So let me dive into it a little bit more.

So under VA regulations and policies, all inventions must be disclosed to the VA even if disclosed to your university affiliate. So even if your invention is not patentable, you're still required to submit a VA disclosure. Federal law and regulations concern, concerning inventions made by VA employees regardless of whether or not the invention is patentable, require that a disclosure be made.

Even if an invention is found not to be patentable, the VA can pursue other opportunities with a commercial partner to further develop the the invention. Specifically, a Cooperative Research and Development Agreement, CRADA, provides management of any new discovery or intellectual property that may result from the collaboration. Next slide.

So even if the VA made no contribution towards an invention, i.e., the invention was made entirely outside official working hours unrelated to VA employment, and with no use of VA facilities, or equipment, a VA disclosure is still required by federal law.

So following receipt of a disclosure, the Technology Transfer Office will review the file, and make a recommendation regarding ownership, and submit it to the Office of General Counsel or OGC. OGC will then review the facts presented in the disclosure and issue a legal determination of rights. The next slide.

So, should adventures – should inventors refrain from publishing papers or making oral disclosures before a patent application is filled? Inventors must take extreme care not to disclose information that would enable someone skilled in the technology to which the invention pertains to make, and or use the invention.

Public disclosure could include talks, lectures, poster presentations, newspaper, or even newsletter interviews, all publications, public use sale, or offer to sale of the invention. Disclosure of any information prior to filling appropriate paperwork with the Patent and Trademark Office voids all international patent rights. Domestic U.S. patent rights are voided if appropriate paperwork is not filled with the PTO within one year of disclosure of pertinent invention information.

And we have some additional information here for where to reach the VA Technology Transfer Program, as well as links, and additional resources to, for instance, the Specialty Team – advisory – Advising Research, or STAR, is a legal team dedicated to research issues as it relates to patents and intellectual property. Next slide; back to you, Cathie.

Cathie Plouzek: Thank you, Kevin. So once the project is underway, we understand that some things may need to change. So you, you've got funding, but something happens, and you need to make a a modification in either your procedures, or personnel, or or your funding distributions.

So we have instructions and forms on our website. But just to let you know, that we are in the process of modifying our project modification process so that it will soon be a, the project modifications will soon be submitted through the ART mechanism.

So please, we would suggest that you contact your Scientific Program Manager prior to submitting a project modification, which is always a good heads up to them, anyway, that you will be, that you have an issue with your project so that they know in advance.

So, if please note that, once your project starts, we now have your budget based on fiscal year, based on your project start date. So we now will need your budget in fiscal year rather than project year based on your start date. And so, and Finance is not able to do anything about your budget if the fiscal year has already passed.

So they are only concerned with project modifications for the current and future fiscal years. So and again, if you have questions about that, please talk to your Scientific Program Manager.

And in another note, you have an annual report through ERA, your RPPR. And please know that including changes in your RPPR is not, does not take the place of a project modification. And if your Scientific Program Manager

sees a, something that needs a project modification with, when they're reviewing your RPPRs, they will be contacting you about that. The next slide, please.

So, for best practices for fiscal management, we recommend that you maintain regular communication with your ACOS and your research administration. We want you to review your budget reports monthly to identify and remediate problems early. We, these, and if there are issues with your, with your study, we would like you to be in contact with your Scientific Program Manager. Next slide, please.

And on this slide, we have the list of current Scientific Program Managers, and you can contact them directly if you have a question. Whether or not who your Scientific Program Manager is, please feel free to contact any one of us. We're, try, happy to direct you to the correct person.

We know that there have been a lot of changes and we've, welcome the addition of Kevin and Lynne on the HSR&D staff. And so and we are hoping that we'll have some other, another Scientific Program Manager soon to fill out our staff. So on the next slide, please.

If you have administrative or business questions that either you or your Administrative Officer have, you're, you're, feel free to contact some additional people. If it's questions about CDA, Robert Small is always the best resource. QUERI is Melissa Braganza.

If you have questions about the JIT process or anything about that, that you're, just as an administrative side, Tiffin is your resource. Lynne Padgett has taken over OMB exemptions, as you noted in this presentation. Intellectual property questions could go to John Kaplan, and Central IRB to Don Workman.

And just if you have general questions, you can always submit questions to the Scientific Review mailbox that's listed at the bottom of the chart.

So right now, the next slide, please. I think, I'd like to thank you for joining us today. And we hope that we can answer some of your questions. So do we have any questions in the Q&A?

Heidi: We do have a few questions that have been submitted. If – give me just a second here. For the audience, if you do have any additional questions, we do have some time available here for questions. Just submit those into the Q&A screen, and we'll get those asked on the call here. The expression D, A, P was used. Can this be defined?

Tiffin Ross-Shepard: It's the Data Analysis Plan.

Heidi: Thank you. I have somebody messaging, and, yeah, the session was recorded.

We will be sending that link out to everyone as soon as that is posted.

Next question here: If a person has clinical responsibilities in their VA job but none in the study, would you expect us to check, "Yes," for clinical responsibilities?

Cathie Plouzek: Yes, yes. If you, if your position is, has clinical responsibilities, what we're looking at is how you're paid. So if you have clinical responsibilities, we want to know that, not not what your responsibilities are on the budget in this particular project.

Heidi: Great, thank you. Next question here, "Are clinicians on GS scale like other VA staff or do they go by a different scale?"

Cathie Plouzek: Physicians may go by a different scale, but we want you to estimate based on the VA scale. I mean, you can also, pharmacists are also on a different scale. But we – you can put in what they are, but we we need an estimate so that we can configure out what the percent IPAs are on a project.

If you have questions about it, talk to your Scientific Program Manager.

Heidi: Great, thank you. We got a clarification comment in here. 2,500 per year is the max for consultants. You said 250,000.

Cathie Plouzek: Sorry, yes.

Heidi: Okay, next question here. When union approval is needed for 1 VISN, it can be difficult to find the correct VA staff to submit the union memo. Do you have contact information you can share or thoughts on how to find the correct person?

Tiffin Ross-Shepard: Unfortunately, we don't have a list of the VISN Hrs. I know that, and the only thing I can do is recommend you contact your local HR. And they should be able to direct you to the VISN HR. That's the only guidance we really have because we don't have a contact list for all of them.

Heidi: Great, thank you, the next question here. If enrolling more than one, one type of non-Veteran is more than one waiver needed or can a single waiver cover multiple kinds of non-Veterans, employees, caregivers, for instance?

Tiffin Ross-Shepard: A single waiver can cover all of the types of non-Veterans if it's for the same project. So on that form that you'll be filling out, you'll put what the project is. And then in this block, you can explain who will, for the explanation, what, who you're asking the waiver to cover. And who you will be enrolling that are non-Veterans.

Heidi: Thank you. Are contractors required to submit inventions to Technology Transfer Office?

Cathie Plouzek: If you have a question about whether or not it's an, it is inappropriate, I would suggest that you contact Tech Transfer. They're, they're very helpful and they would let you know whether or not if the, it needs to be documented? But my suggestion is, si to contact Tech Transfer.

Heidi: Great, thank you, next question here. If requesting funds for travel to conference, for example, to conferences for development, are there guidelines for estimates since we submit for actual costs later?

Cathie Plouzek: You can get estimates of cost based on, like, it's the current information if you were to travel using the the current travel systems. It doesn't have to be exact, but we need to have some general information to estimate, estimate what what your costs are going to be so so that we know. So you know how much money to set aside in your, in your budget, so.

Heidi: Great, thank you. We did get a couple of questions about the slide deck and hands up, handouts. The link to that was included in the, in the reminder that was sent out to you this morning. It was working when we sent that out. And right now, it looks like it's throwing a 404 error.

To give us an hour or two, we should have that corrected, and you'll be able to download the handouts from there. It looks like that is all of the questions that we've received in here.

And we just want to check with our presenters to see if anyone has anything they want to add or any closing remarks before we close the session out?

Cathie Plouzek: Thank you, Heidi. Yeah, if you have any questions that come up later, or that were not addressed, please feel free to contact your Scientific Program Manager or e-mail it to our Scientific Review mailbox, which is VA, vhascoscirev at VA dot gov.

And we'd like to thank you all today for joining us. And we hope that we answered some of your questions so that you'll be able to complete JIT quickly. I can't emphasize enough, how important, particularly this, and now for, and for you to complete JIT quickly. Because we don't you to be caught up in the closure of the JIT database.

So thank you for your attention, and we'll look forward to hearing from you during your, the JIT process. So thank you.

[END OF TAPE]