Cyberseminar Transcript

Date: May 11, 2020

Series: HSR&D Administration Seminar

Session: Just-in-Time: The Final Frontier

Presenter: VA Central Office Staff

*This is an unedited transcript of this session. As such, it may contain omissions or errors due to sound quality or misinterpretation. For clarification or verification of any points in the transcript, please refer to the audio version posted at* [http://www.hsrd.research.va.gov/cyberseminars/catalog-archive.cfm](file:///C:\Users\VHASLCMyersK\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.IE5\73RXHSNF\l)

Dr. Cathie Plouzek: So I’m Cathie Plouzek. And joining me today is Tiffin Ross-Shepard, Emily Evans, and later in session we’ll be joined with Liza Catucci from RAO, Danna Bastien from Finance, and Bob O’Brien who’s a Scientific Program Manager. And they’ll be helping out with the Q&A. So now that your project has been recommended for funding you’re about to embark on the just-in-time process. This process puts all the legal documentation in place to start your projects. It’s not quick or a small obstacle. But requires attention to detail and persistence to get your project started.

So this is just some of the things that we’ll be talking about today, a quick overview of the information that we’re, that will be presented. But first before we start on this, the agenda, we’d like to know who’s in the audience. So we’re going to have a poll.

And our first poll is what is your role? Are you a principal investigator, a budget financial analyst, an administrative officer, or a project manager, coordinator, or other support? Heidi.

Heidi: Yes, responses are coming in. We’ll give everyone a few moments to respond before we close the poll out and go through the results here. Just waiting for it to slow down a little bit. So we’re still moving. Okay it looks like we’ve slowed down so I’m going to close this out. And what we’re seeing is 43% of the audience saying principal investigators, zero budget or financial analyst, 11% administrative officer, and 46% project manager, coordinator, or other support. Thank you, everyone.

Dr. Cathie Plouzek: Thank you that’s very helpful to us. I’m glad so many of you are PIs and project managers have joined us.

So our next question is, what’s your level of experience working on HSR&D project funding requirements? Do you have any experience, beginning level or intermediate or advanced level?

Heidi: And responses are coming in. Again we’ll give everyone a few more moments to respond before we close the poll out. Okay looks like we’ve slowed down here. So I’m going to close this and what we’re seeing is 15% of the audience saying that they have no experience, 41% have a beginner or novice level, 32% at an intermediate level, and 12% at an advanced level. Thank you, everyone.

Dr. Cathie Plouzek: That’s great. That’s very helpful to us. I’m glad that we have some people with experience there are some changes that we want people to be aware of. And we also, it never hurts to review but it’s, it is something new that we need to go through every single time.

So our next question is, what your level of understanding is about the JIT, JIT budget or JIT documents? Who do you, who should you ask when you have questions? Your administrative officer, a colleague, a director, or your scientific program portfolio manager?

Heidi: My screen is frozen. I’m trying to get someone else to open the poll up here. Oh, mine just went so okay here we go. Sorry. Okay, poll is open if you guys could respond. Sorry, with this working from home thing we have these bandwidth issues that pop-up every once in a while and my poll didn’t want to open up. But we’ve got it open, I’ll give everyone a few more moments to respond before we go through the results here. Looks like we are slowing down here. I’m going to close this out. And what we’re seeing is 48% of the audience saying administrative officer, 13% colleague, 2% director, and 38% scientific portfolio manager. Thank you, everyone.

Dr. Cathie Plouzek: Thank you. So we prefer when you have a question regarding your budget or some of the JIT documents that you ask your administrative officer. They have some of the most reliable information. We also would like you to contact your scientific portfolio manager with, if you have questions about information.

Let’s go to the next, so the next poll is, I indicated a start date on my application. Is that when I will be allowed to start my project? And we have three choices here, yes, yes but only if my project clears JIT by the date, or no.

Heidi: And responses are coming in. We’ll give everyone a few more moments to respond before we close it out and go through the results. Looks like we’ve slowed down here so I’m going to close this. And what we’re seeing is 1% saying yes, 94% saying yes but only if my project clears JIT by that date, and 4% say no. Thank you, everyone.

Dr. Cathie Plouzek: Thanks. So the majority of you are correct. Yes you can start on that date if your project clears JIT. But one of the, the most common misconception is, is that the start date is when, is that, what’s on your application. And that is incorrect. You have to complete all of your regulatory documentation before you can receive funds and get a start date. You’ll need to discuss your start date with your scientific program manager.

So there is some information that you need for once you do start JIT or complete JIT on the selection of start dates. First of all you can only start on the first of the month. There are also blackout dates that you need to take into consideration on, in trying to complete JIT. And these happen when the, at the end of the fiscal year when the databases are shut down in September. In September no one has access to the databases so we cannot process any new starts. So if you wanted to start in August, September, or October because of those financial databases being shut down you have to really clear JIT by August 1st to get that in place. In addition, you need to consider that if there’s a continuing resolution it may also prohibit new starts. And so you may have to take that into consideration as well as to when you may start. So I’d like, if Tiffin is on the line I’d like to pass this onto her. I’m not sure that she is\_

Tiffin Ross-Shepard: I am on the line. Can you hear me?

Dr. Cathie Plouzek: Okay. So Tiffin\_

Tiffin Ross-Shepard: Wonderful.

Dr. Cathie Plouzek: \_like to take the next slide please.

Tiff Ross-Shepard: Perfect. Thanks, Cathie. Good afternoon everyone. Just so you know the JIT areas will be open to you by the end of this week. You have 180 days to complete all the JIT documentation without a time extension waiver. Now while this seems like adequate time to complete the JIT areas things tend to take longer than expected. So we want you to start right away. If your project requires IRB you need to start that immediately. You’ll hear that a couple of times throughout this presentation. If your project requires Central IRB you will need a waiver since it typically takes nine to 12 months for Central IRB approval. And then you need your local IRB approval before the ACOS can sign off on the project. Even if you think the IRB approval is not needed 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. Next slide.

Dr. Cathie Plouzek: Thanks, Tiffin. So I’m going to go through some of the budgets which is one of the first things that you’re going to be submitting. You’re going to be submitting a revised budget within two weeks of submitting JIT opening. And this is what the summary budget table looks like. We do not use the budgets that were submit, in the application please do not include those colored budget grants.gov budgets. We only use these revised formats that includes also a budget justification. The budget template and guidance will be available in JIT and can also be obtained from your scientific program manager. This is the template and in any budget you’ll need a version date, the date of the budget. You’ll need to complete all of the top pink area with the title, your name as a PI, the duration in months, and the original budget that you were approved for. And you’ll notice in this form that we have a primary site and additional sites. So any, if you have any secondary sites they will be listed here below.

So in the budget summary table we’ll take it down into different sections. So in the primary site we want the PI listed first and the list of where the primary site is. And you list the city, state. We don’t want just the VA or something else. We need the, where the facility is located. We also need to know whether or not you have a clinical appointment or clinical responsibilities and we need that included in here. HSR&D for our project budgets in JIT we require the project to be in project years not fiscal years. This is different from project mods or from QUERI but for the initial budget since we don’t know what the start date will be, we will just do it in project years. The final budget should closely reflect the original budget and you cannot increase the budget unless you have permission from HSR&D.

So make sure that you include the degrees of all of the personnel. And we need step and grades. Please note that even if they aren’t, someone is not receiving funds we need their step and grade. This is important for some of the calculations that we need to do. There is a maximum of a 2% cost-of-living COLA that’s allowed between years. If someone’s salary has a step increase it needs to be included. You may do that but you need to include it in that person’s justification as to why the increase is above the 2% COLA. All PIs and the site PIs have to be, have an ePromise account in order for money to be transferred. And they need to be a 5/8th’s employee unless there’s already a waiver that has been approved by HSR&D. And also we need the justification and the table to match. Seems simple.

So this is, in our budget guidance that will be available in JIT, we will have this table will be available at the end to allow you, to show you who can receive funds and who may not. There is, there are some exceptions to this, in that physicians and dentists, where it says physicians and dentists may not receive salaries from medical reasons appropriations 824 research funds from HSR&D; this is not entirely true. There are some exceptions. If they are a Career Development Award they may receive salary support from those, from that program.

Some budget table highlights would include not requesting salary for licensed medical professionals with clinical responsibilities. And if you have any questions about any of the budget guidance please contact your SPM. Please only list VA employees under personnel. Non-VA staff should be identified in, as non-VA and listed in the budget table under other.

In the personnel justification we need information similar to what is presented in this example. So we need the name, their degree, what their role is, how much effort they’re putting into this, and their grade, step, and their 8ths from the VA. So we need all of that information at the beginning of each person’s entry in the budget justification. We also need what their responsibilities will be on this project. So we don’t need a huge biosketch on anyone. We just need to know what their responsibilities are.

For the additional sites we need personnel to be grouped by site. So if you have several different sites we want all of the sites to be grouped together. And the PIs for each of the sites to be listed first. VA employees cannot be paid as consultants and physicians may not be paid as consultants. There is a limit of $500 per consultation and $2,500 per year. So, and you need to clearly explain the involvement of the consultants in your justification.

For equipment and supplies. We need you to itemize separately in the budget. And if it’s something that sounds like IT please note in the justification that you’ve already consulted with the local IT and confirmed that it’s not IT. If you are requesting equipment that’s allowed you need to indicate the disposition of that equipment after, at the end of the study what’s going to happen to it. We cannot provide funds for office supplies since these are provided by your medical center but if you have project-specific supplies that are not available from the medical center please note this in the justification. Audio voice recorders must comply with the OIT requirements and we also need to know the disposition of that equipment after the project in the justification.

For travel. In the budget table it is just a summary of the budget allocation but in the justification section you’ll need to break down in the budget a detailed information of how that travel, how those funds are broken down as to travel, per diem, hotel, and so those funds will be held until they are requested. HSR&D has one request per HR&D to present final results. If you are, if it’s a multiple PI it’s still one PI to present the final results.

So we do not, cannot authorize travel for non-VA employees. If an IPA needs to travel it needs to be rolled into their IPA allocation and comply with GSA’s instructions and travel policies. If you have a meeting, project meeting that’s included in the budget again funds will be held until the specific information is needed, details. And if you are organizing a meeting and if it’s a large meeting then you may need to contact EES to get guidance on how to get that meeting approved.

So for professional travel, if you’re affiliated with a COIN you need to submit your request to your COIN Research Office. If you’re not affiliated with a COIN we allow a PI or designee to present their findings. And any travel needs to be included in the budget.

So for other direct costs. We manage an intramural program so as expected that VA staff will be hired to perform the research and provide the needed expertise. If, so we have a limit on the number of IPAs that are allowed. For COINs they cannot exceed 30% of the proposed budget and 40% for non-COINs unless you’ve received a waiver during the proposal 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 may not be contracted but you may contract for other services. When you include a contract describe the service and do not identify individuals who will provide those services in the contract. Please note, the site where the funds for the IPA contract will be sent not the location of the IPA or the contract. So if you’re hiring an IPA at Vanderbilt you don’t put Vanderbilt there you would put whoever is, has that IPA arrangement with that institution.

For subject, participant payments. Participant payments terminology is important. We can’t accept budgets with terms identifying payments as incentives or reimbursements. If the project plans to compensate non-physician VA employees for participation in research the need, the research team needs to contact their local OGC STAR, that’s the Specialty Teams Advising Research. And it’s recommended that they do this prior to IRB submission. Payments to physicians or VA employees for serving as research participants are not authorized unless participating outside the 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 is calculated. In addition, note how the payments are going to be made to the study participants like canteen gift cards, Visa cards, checks, and note that in the justification. Also that any unused participant payments must be returned to HSR&D.

If you are doing transcription as part of your study in your application, in the RFA you probably notice that we requested that you get a quote from the Centralized Transcription Program. The use of the Centralized Transcription Service Program is not mandatory but we still require you to contact them for a comparison quote as part of the process. If you decide you don’t, that you have a service that you would prefer please just provide us in your budget justification a brief summary of the reasons for not using the CTSP in that justification. If you decide you do want to use CTSP and the quote is more than six months old you are required to obtain a new quote. These, the quotes need to be appended to the budget justification. This allows for the transcription service to prioritize the work that is being requested.

So if you are using the CTSP when listing it in the budget if Salt Lake City is not already a research site then you’ll have Salt Lake City added as an additional site in the budget with Susan Zickmund listed as the site PI. Susan Zickmund’s effort should be not applicable and her salary is contributed. And in the August 2020 RFA for IIRs we list the budget justification guidance and so that you know what needs to be put into your budget justification. In addition, under other you would need to list the transcription services along with the associated funds on the budget table. If Salt Lake City is already a research site you don’t need to include Susan Zickmund as the PI or co-I. You just need to add under other the CTSP Transcription Services along with the associated funds with it.

So research funds are not used to pay for IT. The VA has separate IT appropriations which is not controlled by research. If you have devices such as laptops or tablets that are going to be used for patients only they can be considered patient medical devices and thus non-IT. But if the devices are going to be used by both patient and personnel it’s considered IT and has to be included on the IT budget. IT has approved that voice recorders can be purchased with research funds though. If you’re requesting IT funds ask your local CIO to sign off on the request indicating your ability to provide funds and include this in the budget. If you purchase GoToMeeting it has to be approved by the local CIO before the funds can be provided. There’s some software that is approved for research funds as it’s considered scientific computing and that, but SAS and SPSS are available in the VINCI platform so they are not approved for purchase. If you have any questions about it you can see the memo regarding the guidance on this software that’s available at that, the research link.

When you submit a revised budget always include the version date in the header of the document, here and note the duration of the study. Always include both a summary budget table and the budget justification. We can’t accept one without the other. Please include in your budget justification if you’ve made any budget updates based, they need to be summarized at the beginning of your budget justification and included in the budget justification narrative in the appropriate places. So now I’m going to turn this back over to Tiffin who’s going to discuss some of the other JIT pre-funding documents.

Tiffin Ross-Shepard: Thanks, Cathie. Okay so for all studies you will need to complete JIT documentation. For all studies we require that the PIs complete and submit a PI assurance form that the primary site ACOS will complete an assurance form which requires IRB review or determination that IRB is not needed and R&D Committee approval. If IRB is needed, is not needed I’m sorry the IRB determination is required to be uploaded into JIT. You’ll also need to provide a quad chart that includes a Gantt chart of tasks over the project period as well as budget information. When appropriate you may also need to complete additional JIT documentation. Most common of these are union notifications if you’re surveying employees, the OASC review for national surveys, an OMB exemption if interviewing or surveying Veterans, clinical trial registration, and DSMB plan approval. Next slide.

The PI assurance form attests to the PIs agreement to comply with VA policies and reporting. Also all site PIs must be registered in ePromise. With respect to the ACOS assurance form, this form attests to the completion of the review by the R&D Committee and subcommittee including IRB review, as well as the PIs eligibility. Next slide.

A VA facility is considered to be engaged in human subject research when someone with an appointment at that facility obtains one of the following for the purposes of the research study. First would be data about the subjects of the research through intervention or interaction with them. The second would be identifiable private information about the subjects of the research. And then third would be the informed consent of human subjects for the research. If IRB oversight is not required or is not applicable then the R&D Committee approval only needs to be submitted with the ACOS form. And as I previously mentioned the IRB’s determination that IRB oversight, if it’s not required that form must be uploaded into JIT.

If you’re not certain if your project requires Central IRB please contact your scientific program manager and discuss this with them, your study and this aspect of the study with them right away. Please remember that Central IRB takes a significant amount of time to complete so you need to start this immediately. In fact we encourage you to get your IRB information submitted as soon as possible so that you don’t have to wait and there’s not a delay. Again if you have any questions about this contact your scientific program manager or specific questions can be sent to the Central IRB. And you can just contact their office directly.

Dr. Cathie Plouzek: Thanks, Tiffin. So all projects require a quad chart. It’s just a brief snapshot of the study asking about the aims and the outcomes anticipated. In one of the sections is a timeline. And this often is the most, this is the section that causes the greatest issues and when you submit this we really want something that’s similar to a Gantt chart. We don’t want to see aims one, two, three, year one, two, three, and just some excess. We want to know what tasks are going to be completed over the timeline of the study. So now I’m going to turn this over to Emily Evans.

Dr. Emily Evans: Thanks. So I’m going to discuss some of the requirements regarding projects that involve data collection first from VA employees and then if your study involves data collection from Veterans and caregivers. But we’re going to start first with data collection from VA employees. So first, talking about union notifications. So prior union notification is required for all data collection so that’s both interviews and surveys involving VA personnel when asking bargaining unit employees about conditions of employment. So it’s very important to remember that clinicians including physicians may be unionized employees. And in terms of understanding what constitutes conditions of employment HSR&D takes a strict approach and generally requires union notification anytime a survey or interview will be administered. Because conditions of employment can reasonably be interpreted somewhat broadly to include questions about an individual’s decision-making process in the implementation of an intervention or impact on their work. This slide outlines the three levels of union notification and the process for satisfying to JIT requirements. So if you’re only surveying or interviewing individuals within your facility, facility-level you contact your local HR. Within a single VISN you contact your VISN HR. And if you’re going across more than one VISN you have to submit a national union notification packet to ORD and I’m going to talk about that on the next slide.

So national union notification. So what happens is that you will compile all the requested information listed here into a single PDF file. You’ll upload that into the miscellaneous JIT area and email it to the JIT address. This includes a copy of the survey or interview questions, the site, a brief description of the study, what participation entails, types of data being collected, and the study team contact information. So HSR&D works with the Office of Labor Management Relations, LMR, to have the national unions notified. Generally you’re required to note that the survey or interview must be voluntary, anonymous, and confidential. That should say the, that language should be included on the copy of the interview guide or the survey. But anonymity is always, not always possible so you’ll need to, if that’s the case, include a statement that one, explains why participation cannot be anonymous, explain what steps will be taken to protect the identity of the respondent, and three, state that follow-up is voluntary. Once you’ve compiled this information and send it HSR&D we review, we send it to the Office of Labor Management Relations who work to have the national unions notified. Once they have been notified we receive a concurrence that we forward back to the study team and then that gets uploaded into JIT. Okay.

Also if you are in terms of data collection from VA employees, and this is just surveys. So union notification deals with surveys and interviews. The Organizational Assessment Sub-Committee, OASC, deals only with interviews whether their web-based or paper. It does not deal with interviews. OASC review is required if the study meets at least one of the following two criteria. And these have been recently updated. So if the survey is going to be administered to 10,000 or more VA employees or administered to VA employees across 20 or more sites OASC review is required. Again, it’s only for surveys and surveys of VA employees not Veterans. And the link at the bottom provides additional guidance.

Again so you would send, if your surveys have IRB approval and need OASC review you send those to David Mohr at the address listed here. Surveys that do not have IRB approval you send to the email address listed there for review by the subcommittee and a response is typically provided within a few weeks. And the rest of this slide outlines what information you need to provide in submitting that request for OASC review.

And so now I’m going to talk about data collection Veterans and caregivers. So OMB review and approval or exemption from OMB review is required prior to conducting surveys and interviews for all projects involving data collection from 10 or more individuals who are not VA employees. Generally Veterans and caregivers. Generally HSR&D funded studies can have an OMB exemption where it does not require full OMB review. This is an internal process that requires the investigative team to submit, to fill out a background information template too so that the scientific program manager can then provide an OMB exemption brief that explains how this data collection benefits clinical care and how the survey or interview is not duplicative. There’s a template that’s provided in JIT that asks for information about the project overview, the justification for exemption, and the justification that the study is not duplicative. So follow the template provided closely and be specific and concise in providing the requested information.

And on the next slide I just want to briefly review the criteria for OMB exemption. So a study only needs to meet one of these criteria. So it needs to either be a clinical trial, meeting ORD’s standard definition of what constitutes a clinical trial. A clinical examination, direct treatment, prevention of a clinical disorder, or interpretation of biological analyses. I’ll just note that for most HSR&D funded studies that are not clinical trials the prevention of a clinical disorder is the most regular reason for an exemption they’re OMB requirements.

Okay. So moving on from data collection to registering your study. So public registration and reporting of clinical trials is an expected part of sound scientific practice and it may also be required by federal law and in some cases, and it’s also required by most journals if you wish to publish your results in those venues. ORD has a specific definition of clinical trials that is adopted from the International Council of Medical Journal Editors defining a clinical trial as any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on outcomes. The studies that meet this definition and based on consultation with your scientific program manager will need to register and then later report results to clinicaltrials.gov. We have a very specific process for how this is done so you know first you consult with your SPM to determine whether the study meets the definition and should be registered. You wait until all other JIT requirements have been met. And then finally once all the other JIT requirements have been met you will receive an email from ART requesting that you go through their process to register your study with clinicaltrials.gov. Do not register the study on your own or until you receive the emails from ART. So ART will send you an email, it will go to your VA email and you should use that process to register your study.

As a reminder if you have a clinical trial you need to maintain your recruitment and retention tables, such as the one shown here. Standardized collection of these data should already be occurring as part of your research. And this table shown here should be included for any discussions with HSR&D regarding the status of your project as well as end project modification request.

And then finally I would like to talk about the HSR&D Data and Safety Monitoring Board, or DSMB. So the DSMB provides ongoing evaluation of a study’s progress including accrual and retention, monitoring of adverse events, and the adequacy of the analysis plan. This is accomplished by an independent review board that HSR&D has chartered and meets at specified intervals and requires routine reporting from the PI, so either mid-year or annual reporting. Whether your study reports to the HSR&D DSMB is determined by the SPM at the time of funding decisions. So projects referred for review to the DSMB are required to submit a Data Analysis Plan or DAP for review by the DSMB. In very rare occasions after review of the DAP the DSMB may determine that a study does not require further monitoring by the DSMB but generally studies have to continue to report annually to the DSMB.

Some of the criteria for DSMB referral are listed on this slide. So clinical trials, studies in which prior data suggests intervention being studied has potentially unacceptable toxicity, high-risk, phase two trials and phase three studies with the exception of low-risk behavioral, and nutritional studies.

But again the decision for DSMB referral is determined by the SPM for these with the following characteristics may also be referred to the DSMB for review. So if your study is recruiting from multiple locations, even within a single VA Medical Center or has potentially complicated analytical plans. Low-risk studies may be referred to the DSMB if the studies are exceptionally large, long-term, or involve vulnerable subjects. There are a few cases in which oversight may not be required but the DSMB not the PI determines this. So if you have, for example, a multi-center high-risk phase one clinical trial that has clear and objective criteria for halting dose escalation if unacceptable side effects are observed. Or clinical trials that are expected to accrue too quickly to allow for the DSMB to be constituted and complete data and safety monitoring. But again this is determined by the DSMB not the PI.

So you will have to submit a Data Analysis Plan in JIT. They should be uploaded into JIT within 45 days of JIT opening. The DAP details, the study design, and analysis plan with respect to the research questions and a plan for how to monitor and track serious adverse events. And this slide lists required DAP elements. Also because we’ve modified the JIT requirements for this so that uploading the DAP into JIT clears this requirement and then the DAP is reviewed outside of the JIT process, you do need to include a statement of assurance with the DAP document that you agree to refrain from recruitment activity until a DSMB DAP approval has been received.

Now I will turn it\_

Dr. Cathie Plouzek: Thank you, Emily. Thanks. So now we’re going to talk about pre-funding project modifications. During the funding process a lot of things can happen. A Central IRB may require changes in your study sites, of personnel, or methods. Or there may be some personnel changes, somebody’s retiring, or people move. So during this, since you’ve submitted your application if you have changes in your project you’re going to have to submit a pre-funding project modification. First thing you’ll need to do is contact your scientific program manager to explain why a change is needed and to request the modification form. This form will be uploaded into JIT for you into the miscellaneous section and this form is a modified project mod form so no ACOS assurance is needed at this point. Just the PI’s signature. But please provide adequate justification as to what the changes are in your project. And once approved if there are required changes in JIT those modifications will also be made.

So we’re going to go onto our last poll. And this is on intellectual property. Who must disclose intellectual property to the VA? Salaried employees, an IPA, a WOC appointees with research responsibilities, dual appointment personnel, or all of the above. Heidi.

Heidi: Yeah. Again we’ll give everyone a few more moments to respond before we close the poll out and go through the results here. And looks like we’re starting to slow down here. So I’m going to close this out. And what we’re seeing is, the audience is saying 5% salaried employees, 0%, IPA, 2% WOC appointees with research responsibilities, 0% dual appointment personnel, and 94% all of the above. Thank you, everyone.

Dr. Cathie Plouzek: Thanks. That’s great. I’m glad that the majority of you understand that intellectual property, we all have a responsibility to report it.

So under VA regulations and policy all inventions must be disclosed to the VA. Even if it’s already disclosed to the university affiliate. Even if your invention is not patentable federal law and regulations require the disclosure be made. And you know if the invention is not found to be patentable the VA can also pursue other opportunities with a commercial partner to develop the invention. Specifically a Cooperative Research and Development Agreement, a CRADA, provides management of new discovery or intellectual property that can result from the collaboration. Even if VA made no contribution towards the invention and this was completely outside of official working hours and unrelated to employment and there was no use of VA facilities or equipment the VA disclosure is still required by federal law. And the Office of General Counsel will review the facts and issue a legal determination of rights.

One thing as scientists, inventors should be, refrain from publishing paper or presenting oral disclosure before an application is filed. We need you to take extreme care not to disclose publicly in talks or lectures or interviews or publications until you’ve had the appropriate work filed with the Patent and Trade Office or with our tech transfer program. So we would encourage you to be in contact with the tech transfer program. Their contact information is detailed on this slide and they can advise you on how to proceed with any intellectual property as the results from your work.

So as we all know there, once your project’s started there may be some roadblocks. There may, you may find that you need personnel may change, you may find that you need to change your recruitment strategy, your methods, or have to reorganize your budget. There is a project modification process that can be accessed on this page once you get started. You will be having to submit an annual progress report through eRA Commons the RPPR. This is not a project modification mechanism. We will, if you just indicate that you have had to make some changes in your aims or personnel your, and you haven’t submitted a project modification it will be flagged and you’ll be receiving contact from your scientific program officer regarding your report.

So the best practices for fiscal management of your project is to maintain regular communications with your ACOS and your research administration, review your status and your budgets reports monthly to identify and remediate problems early. Please keep in mind once you start your project if you have a project modification again our financial system shuts down in September so you need to get the, if you’re nearing the quarter of the fiscal year, the last quarter and you still have funds that you need to redistribute or make some changes you need to do that early. Because we, there comes a point where we cannot do anything regarding project modifications. If you have any questions contact your scientific portfolio manager.

So this is a list of people if you have administrative or business questions and their contacts. We have finance, JIT management, you have CDA questions, QUERI, OMB, union notification, waivers, or intellectual property. So all this information is available here for your reference.

Also the list of scientific program managers is also listed on this page and their contact information.

So now we’re going to move into questions. But I would like, before we start I would really encourage everyone to download the slides from today and use them as reference. This is a lot of specific information and very detailed and so please do download that. And the recording will also be made available later on. And be posted on the HSR&D CIDER archives of recording. So Heidi could you please open up the chatbox so that we can take questions now.

Heidi: Just one clarification here. The questions, please use the questions pane to submit questions. The audience doesn’t have access to chat. So please use the questions to submit questions to us. And I can start at the top and work through what we have received to this point. Can you please clarify again the maximum allowable costs for consultants?

Dr. Cathie Plouzek: So consultants are, there’s a maximum amount of 2,500 per year for a consultant.

Heidi: Okay, great. Thank you. The next question here, please provide clarification of the difference between fiscal year and project years?

Dr. Cathie Plouzek: So a project year, well a fiscal year is obviously from October 1 to September 30th. The project year where we aren’t concerned about the start date. So we’ll just assume that in the first year you’re going to do X, Y, and Z. So when the project actually starts that project year may be, not match the fiscal year.

Heidi: Okay, great. Thank you. The next question here, is an HSR&D summary budget table acceptable with merit CDA submission?

Dr. Cathie Plouzek: Liza, would you like to take that question.

Liza Catucci: Sure. I don’t think Rob Small is on the call. And he’s our mentoring program manager for a CDA. To my knowledge the summary budget table should be acceptable because that’s the standard format that we use for all of our HSR&D funded studies.

Heidi: Okay. Thank you. The next question here, is it sufficient to submit IRB approval for aim one?

Dr. Cathie Plouzek: We would like, we do not want your project to be slowed down. If you are not able to obtain IRB for an entire project we may need to phase your project so that it stops if there is a problem with the IRB in the next phase. One of the reasons why we have all the documentation upfront is to prevent delays to the project. And so we would prefer that all of that, the documentation is complete for the entire project otherwise we would, we’ll probably establish a phasing.

Heidi: Okay, great. Thank you. The next question here, if you are not doing research such as for the innovations planning grants mechanism can the ACOS add a station form check N/A for research if it is determined that there is no research being conducted?

Dr. Cathie Plouzek: Liza.

Liza Catucci: Heidi, can you repeat that question I’m not sure I heard it entirely?

Heidi: Sure. The question is, if you are not doing research such as for the innovation planning grants mechanism can the ACOS add a station form and check N/A for research if it is determined that there is no research being conducted?

Liza Catucci: [inaudible 59:15] determined that there’s no research being conducted that should be something that [inaudible 59:20] in the protocol itself. In which case we wouldn’t necessarily assign that location as a site for their research. There’s no research being conducted we shouldn’t be sending any money there. The funding of that particular [inaudible 59:35] it’s about the primary site is what triggers [inaudible 59:37] to be opened up in JIT. So if whatever is occurring at that site is not research and there’s no money then there would not be a need for us to open that area in JIT and therefore we wouldn’t require an ACOS assurance or a PI assurance.

Heidi: Okay. Thank you. The next question here, can you talk a bit about quadrant three and what is meant by graphic for that section?

Dr. Cathie Plouzek: So generally in quadrant three we want an illustration of what your project will entail. Generally that comes from a graphic within your project. So, but we want something so that we can easily show this to a director and they have some concept of what the project involves.

Heidi: Great. Thank you. The next question here, to understand OMB exemption timeline approximately how long does this process typically take?

Dr. Cathie Plouzek: Emily.

Dr. Emily Evans: The OMB exemption timeline, so as soon as you complete the background information template in JIT and it is sent to the scientific program manager they review and then it is sent to me and then after I review and approve it will be sent to one of the directors in HSR&D. It can happen in as quickly as a week if you provide the correct information in the appropriate format. So this is a fairly quick internal process.

Heidi: Great. Thank you. The next question here, generally speaking do pilot interventions where outcomes focus on feasibility and acceptability require clinicaltrial.gov registration?

Dr. Emily Evans: This is Emily. So they can if they are, they meet that definition of a clinical trial. And we have had studies that are pilot studies be required to register for the clinicaltrials.gov. It is very important they’re linked, linking through your study and registering at clinicaltrials.gov after ART has reached out to you. That you think carefully about what outcomes you are measuring and reporting. Because what you register upfront and say you’re going to report on, you will be expected to report that information at the end of your study. Again it depends on the particulars of the study but just because it’s a pilot does not mean that it’s exempt from that requirement.

Heidi: Great. Thank you. Next question here, if we would like a grant to start on October 1, 2020 and we are applying to Central IRB is it possible given the nine to 12-month timeframe that you provided for JIT approval?

Dr. Cathie Plouzek: It is, it’s possible but highly unlikely because you will need to have cleared JIT by August 1st. So I mean if you, if your study is, meets all of the guidance from Central IRB and you have, you apply right away I mean it’s possible. But you need to work very fast to get it done.

Heidi: Great. Thank you. The next question here, does COVID-19 impact any of the timelines described in this talk?

Dr. Cathie Plouzek: I’m sure. There, will impact some timelines. I can’t really say that we have a good handle on what that impact will be. We don’t even know how, for a particular study how that will impact whether or not a study can start. So I think we have to take that as a case-by-case basis.

Heidi: Great. Thank you. The next question here, for a project that has PI/co-I at multiple sites what determines the IRB of record? Does the IRB at every facility with a PI or co-I need to review the project?

Dr. Cathie Plouzek: Anyone want to take this one?

Unknown Speaker: Liza, yeah.

Liza Catucci: This is, Liza. I’ll reply. Okay so based on the new common rule and the guidance [inaudible 01:05:03] has been sending out to the field going forward VAs or studies that are multisite in the VA need to either be overseen by one of them being CIRB. Locations who are single VA in the field that actually has authority to oversee multisite studies. So that’s going to be up to the PI to investigate whether the primary site for their research in VA is a location that is going to be able to have that authority. And because VA also now allows affiliate IRBs for emergency VA research, as well as commercial IRBs. If your study involves a site that’s engaged with one or the other and they can do multisite review then you would have those options. That’s something that’s going to have to be determined on a case-by-case basis by whether they’re wanting to be reviewed by [inaudible 01:06:06] Central IRB or one of the sites where their study’s participating that has the authority. We can’t really answer that question for you because we don’t know what VA sites are eventually going to have the authority to conduct multisite review. Hopefully that’s helpful.

Heidi: Liza, I need you to call in on the phone line rather than use your computer. You were incredibly difficult to understand. I’m getting multiple [inaudible 01:06:35] from the audience we’re just not understanding what you’re saying. If there is anyone else who could summarize what Liza just said it would be very appreciated. Hello.

Dr. Cathie Plouzek: Heidi, I think I mean basically I think Liza was saying that with the change in the IRB process it’s that we really need to look at it at a case-by-case because we can’t, with, we don’t know what affiliates have, what IRB processes their moving through. So we need to look at this case-by-case.

Heidi: Great. Thank you. The next question here somebody’s asking, did, was it that the data budget document must be uploaded within two weeks of JIT opening?

Dr. Cathie Plouzek: I’m sorry could you repeat that one again.

Heidi: Does the updated budget document, does that need to be uploaded within two weeks of JIT opening?

Dr. Cathie Plouzek: Yes. We would like a revised budget within two weeks of JIT opening.

Heidi: Great. Thank you. The next question here, when should we expect to receive a notice of award after submitting JIT?

Dr. Cathie Plouzek: So, the notice of award, once you work with your SPM on a start date they will process the paperwork and it goes through the approval process. Once that is approved you should receive the notice of award. But you can always contact your scientific program manager regarding that and to see where that is. Sometimes there are some issues with eRA Commons that we have to work out. But if you have questions about whether or not you can start please contact your scientific program manager.

Heidi: Great. Thank you. The next question here, if we need to revise our budget, also need to submit a project modification form?

Dr. Cathie Plouzek: It, that will, for this first revised budget we need you to note any changes in there from the original if there were questions. But at this point the, it would be if there are changes in your aims or your personnel or other things. If there are just slight rearrangements to the budget you need to just document that at the beginning of the budget justification. And if there are questions your scientific program manager was to review the budget will come back and ask you about it.

Heidi: Great. Thank you. The next question here, can unused funds be carried over to the subsequent project year?

Dr. Cathie Plouzek: Danna. Would you like to answer that one?

Danna Bastien: I’m here. I’ve never really worked with rollover funds but from what I understand is that we can as long as the funding is available.

Dr. Cathie Plouzek: I think there’s a certain limit that they can rollover.

Danna Bastien: I believe so as well. I will ask about that information and I will get it to you.

Dr. Cathie Plouzek: Okay.

Danna Bastien: To make sure.

Liza Catucci: Hi, this is Liza. [inaudible 01:11:05] rollover 4% but with COVID there’s a possibility that amount might be increased next year.

Dr. Cathie Plouzek: Right. If you have a large amount of funds we suggest that you’re talking to your scientific program manager and let, talk to them and let them know and you can discuss whether or not you need to submit a project modification.

Heidi: Great. Thank you. The next question here, is a project manager or research assistant considered key personnel? If we have had a change in project manager or research assistant since the proposal was submitted does this need a submission for change in key personnel?

Dr. Cathie Plouzek: Generally for key personnel we consider them to be co-Is that will be essential to get the research completed. We don’t request for program managers or analysts or other things to submit a project modification. But when you’re submitting your budget in the budget justification you should note that the, you’ve had a change in the project manager. It went from this in the original, this person in the original and it has now been replaced by so and so.

Heidi: Great. Thank you. The next question here, what is the protocol for deciding on a start date? A conversation with one’s scientific program manager?

Dr. Cathie Plouzek: Yes. That would be the best place to start.

Heidi: Great. Thank you. The next question here, is there a mechanism to pay Veterans if they act as consultants or stakeholder in the planning of a grant?

Liza Catucci: Hi, this is Liza. If Veterans act as stakeholders or they’re on an advisory panel they can receive a stipend. We have some studies where actually they have a process in place where they make it $100 or so, so that’s something that you could submit a request for that and you’d have to pay them in accordance with what your local VA policy is providing stipend.

Heidi: Great. Thank you. The next question here, in budget justifications is salary information needed by clinical VA investigators that are not receiving salary?

Dr. Cathie Plouzek: Could you repeat that one again?

Heidi: In budget justifications is salary information needed by clinical VA investigators that are not receiving salary?

Dr. Cathie Plouzek: Yes.

Heidi: Thank you. The next question here, is there a guidebook or manual that also includes everything in the slides and more?

Dr. Cathie Plouzek: Yes. Well we provide the slides in the seminar and there will also be, in JIT there is guidance available to be downloaded for each of the different areas. And we will also provide the, a document of JIT guidance and the budget summary table example for you in JIT.

Heidi: Thank you. The next question here, can you please clarify what happens if JIT does not meet the 180-day requirement?

Dr. Cathie Plouzek: Liza.

Liza Catucci: Hi. So you will receive a notice automatically from JIT once you reach 150 days sort of as a warning. If you don’t think that you’re going to be able to clear JIT in 180 days when you get that reminder at 150 days you need to submit information to your scientific portfolio manager with a plan for when you think you will be able to clear JIT. And you’ll have to provide a justification as to why you don’t think you’re going to be able to clear JIT in 180 days. And you’ll have to be sure you provide an estimate of when you think you will be able to clear. Because if we’re going to approve an extension we need to be able to anticipate how much time you need beyond the 180 days.

Heidi: Great. Thank you. The next question here, we are pursuing CIRB approval and given the timeline you mention I anticipate we will need a JIT waiver as unlikely we will get a CIRB approval before 180 days. Can you describe the waiver process further? What information is needed?

Liza Catucci: As I just mentioned, what we need to know is the justification as to why you won’t be able to clear JIT in 180 days. So in this case it could be due to VA CIRB delays in approving the project. If that’s the case then you’ll have to include an estimate for how much longer you think it will take for the VA CIRB to approve.

Heidi: Great. Thank you. I have someone who wants to circle back to when Liza answered the question on the ACOS check N/A if research is not being, doing research there. We were not able to understand your answer.

Liza Catucci: Yeah, okay. Sorry about my phone, no I apologize for my spotty internet connection. So basically what I was saying was that from our point of view what triggers us setting up another site in JIT is funds being sent to that site because research is actually being conducted. So if there are no funds going to that site because it’s been determined by the principal investigator that there are no research activities being conducted there, we won’t even set up that site as a location in JIT so there won’t end up being any ACOS assurance or a PI assurance requirements.

Heidi: Thank you. The next question here, can you remind us of when JIT is opening?

Dr. Cathie Plouzek: Tiffin.

Tiffin Ross-Shepard: This is Tiffin. It will be opening definitely by the end of the week.

Heidi: Great. Thank you. The next question here, is there a way to pay Veterans to attend a planning meeting? You stated no travel is allowed for non-VA employees.

Dr. Cathie Plouzek: Okay when we talked about no travel allowed for non-VA employees specifically we were referring to people who are working in the research under contracts or on IPAs. If the Veteran is part of a Veteran engagement board or a planning group and they need to attend a meeting somewhere we can set them up in Concur and we can pay for their travel that way. As a non-VA person they would have to you know register with fiscal service through their local facility in order to be able to be registered in Concur and to be paid for their travel.

Heidi: Great. Thank you. The next question here, does JIT access come up on eRA Commons? When should we expect to see it?

Dr. Cathie Plouzek: Oh we’re not doing JIT through eRA Commons. So, but we don’t communicate about JIT to the field through eRA. You would be notified directly through emails from JIT through that database as well as information from our office and HSR&D.

Heidi: Great. Thank you. The next question here, do you have thoughts on giving PIs access to JIT document management website as a read-only? This could provide greater transparency around where the process stands.

Liza Catucci: This is Liza. We’ve had that discussion with JIT program managers on a couple of occasions and that’s an ORD-wide decision. We don’t have authority to make that decision for our service only. And while it’s being considered there has been no decision to do that at this point.

Heidi: Okay. Thank you. That is all of our pending questions. If any of you have any closing remarks you’d like to make before we close things down today this would be a great time to do that.

Dr. Cathie Plouzek: Okay. Well thank you for taking time to review the JIT processes. We hope that this presentation assists you in the funding process. And if you have questions we advise you to contact your scientific portfolio manager. We want to fund your awards as soon as possible. So please get started immediately. And thank you for joining us today.

[ END OF AUDIO ]