Mike Wiley: Great, thank you so much for that introduction. So, yeah, I, my name is Mike Wiley. I'm actually an analyst at at Rios Partners. We have been working with the VA, and more specifically, working under Dr. Molly Klote, to develop the Research Law Explorer.

So the Explorer really began with the understanding that there is a lot of legal complexity out there that affects the work that the researchers are doing every single day. So in some initial research that we did across just a few key research related legal topics, we identified nearly 800 laws across all 50 states, as well as D.C., territories, and even tribal lands that might have a significant impact on the way the VA designs, and implements its studies.

And so, the problem with having all of this legal complexity, and having various laws across various territories is that, if you are not an absolute expert on everything legal related in your state, as well as other states, this can create a real headache. Extra work, wasted time just to try to figure out what are the relevant laws impacting your research?

And so, this is something that we we learned when having some initial conversations with VA researchers, as well as staff at the the Central IRB. We realized that there needed to be some, kind of, a one stop shop resource for researchers study coordinators; really, anyone at the VA with a VA dot gov e-mail address to be able to quickly find out what are the relevant laws in their state, or multiple states that impact their study.

And so, especially when a, when users visit this resource, they should feel confident that this is displaying accurate information since it is a VA resource, and not just some random website. They should also feel confident that the information they're seeing is up to date. Because there is a process on the back end to regularly update this tool whenever laws change.

So this really was the thinking behind and the goal of the Research Law Explorer. We have been working with this for several months now. We've been working with a pilot team of ten or so researchers at local VA sites, as well as Central IRB employees. And they have given us some tremendous feedback and taken the Explorer from just an Excel spreadsheet, which is what it was when they first saw it, to what is now a more robust user interface.

And this slide shows some of the the basic functionality of that interface, the ability to search by state, topic, and and keyword. The ability to export information. But really, what I wanted to do today is to do a full demonstration of the Explorer from start to finish. What is it like to go in and find the information that you need? And then, throughout this process I will try to answer as many questions as possible that are related to the interface. So, any question that requires me to have the interface open on your screen, I will try to answer.

And then as Parker mentioned, after all of those questions are done, we will move to a second, more fuller Q&A session in which we answer all of the additional questions that don't require me to have the interface open in front of me.

So with that said, somebody can cut me off, if there are questions waiting for me? But I'm going to stop sharing this screen so that I can go ahead and jump into the Explorer. If you just give me a moment here.

Alright, great, so, now, you should be seeing the landing page of the Research Law Explorer. The very first thing to note on this page is that it is on a website. Just like any other website, you can take this, and you can set a bookmark. Parker mentioned that the link will be distributed to every participant of this webinar. However, just to make sure that you don't have to continue going back to these webinar materials, I highly recommend just setting a a bookmark.

So this is the landing page, it is the first thing that users see. Once you click that link, it will take you straight here. There is no password protection or anything like that. As long as you have a VA dot gov e-mail address, you will be able to get to this page. And there is some additional tabs and things happening up at the top.

The only thing that we are concerned with is this top banner up here, everything below it, as well as these tabs over on the left side. So the tab that we're on right now, it's called the About the Explorer page. And it contains just some basic orienting information.

If you, or somebody, say, it's your first time using the Explorer, or you did not have the benefit of, say, sitting through a webinar to to see how it's done, this contains some orienting information like background, FAQs. And then legal disclaimers, and Contact OGC, the thinking with these last two buttons here is that, really, the Explorer is meant to provide word for word, unedited legal text.

It just wants to show you what the laws are. But if users are looking for more complicated opinions, or interpretations about the laws, they're highly encouraged to contact the Office of General Counsel through their offices, normal processes, or via the e-mail that is provided in this contact OGC pane.

The only, last thing I will point out here is this last updated label will always be there just so users are are confident, like I said, that this is up to date information. And it will continue to be updated going forward.

That is essentially it on this About the Explorer page. From here, users can click the Search for Laws tab on the left side, or click this Go button to get there. So the Search for Laws tab is really the, kind of, main portal of the Explorer. That's where you will do all of the work finding whatever information it is that you need. There's a lot more going on in this page.

I will just start by saying there is now this, a question mark button in the top right corner. If users click this button, they will see step by step instructions for finding the information that they need. But just for demonstration purposes, I will walk you through all that information right here.

So the two main boxes on the page are the Available Laws box, and then the Legal Text box. The Legal Text box is very simple, it just shows you this word for word, unedited legal information. The Available Laws box contains quite a lot more.

So this is every single statute inside the Explorer, which is some 800 rows of information. One statute per row, and every, every one is listed by state, hyphen, legal topic, hyphen, and then the title of the statute exactly as it was when it was passed. So since that's quite a lot, like I said, about 800 rows, rather than scrolling through to try to find the state, and topic that you're interested in, your very first step on this page should be to click the Search button.

And from here, there are some helpful dropdowns to really quickly, and easily select just the information you want. So starting with state, you can select as many states as you'd like. This also includes territories and tribal lands as I said earlier. So you can select multiple, but I expect for for many users, they will just be interested in just one state.

So just for demonstration purposes, let's do California, and just leave it at that. From here you can say, I want every legal topic; I want all the information that you have in California. Or you can select from a few legal topics. So there's animal research, informed consent, privacy, and then, kind of, a a miscellaneous other laws category

And so let's just for demonstration purposes, we'll do informed consent and privacy. And from here, if users want to get even more granular with the search, there are subtopics that fall within what we have just selected, informed consent, and privacy. There is also a date range.

So if you, say, I only want the most recently updated statutes, you could do that. However, if this is your very first time using the Explorer, I highly recommend leaving these last couple of boxes just as they are, just to make sure that you don't miss any critical information.

So let's say we are happy with these selections. We have California Informed Consent, Privacy. Let's click Search. And from here, now, the the Available Laws box has gone from hundreds and hundreds of rows to, now, just this many. And I want to say about 30 or so. And you can see, they all start with California, which is exactly what we want.

And from here, users can just click any one of the rows to automatically populate the relevant legal text in this box on the right side of the page. And so you can read the legal text directly in the Explorer. You can also click on this 'More Info about this law' button which will show some additional information, including title, which is actually the – that was listed at the end of the, this, these hyphens in the Available Laws box.

There is the statute code. The year was updated. If users click this little link here, they can view the the statutory text on a third party website, and then distribute that, that link as they would any, any other link. And then there are these three columns here, other, Link 1, 2, and 3. Most of the time these will appear blank, so don't worry if you're not seeing anything there.

Essentially, we wanted to leave this space just in case there is any information that might be helpful in, in having you understands the statute that you're reading. That might be a link to a secondary statute; that might be a link, say, to an Office of General Counsel opinion. So that space is is there for that, but like I said, most of the time that will be blank.

And then finally, there is this Applies to VA question mark column. So this is very similar, it just takes a a yes or no value. But essentially with, in a collaboration with the Office of General Counsel, we're working to identify the statutes that do affect VA Research. By default, this is, this takes a a yes value. But over time, we're, we're identifying the, these statutes that do not actually apply to VA Research as a federal entity.

From here, we can click away from this box, and continue to click through the different statutes to change the legal text that populates in this box. We can click a row again to deselect it. And so this Legal Text box, Legal Text box becomes blank again.

Another thing we can do is further filter down this list of available laws inside this box by going back to Search, and then clicking on Keyword. So this is a a keyword search, but it doesn't quite work like Google. So with Google, you can enter a bunch of words into a single box, and it will just spit out what it thinks you mean by all that.

Here, it means a very specific thing. So I'll show you. Let's just enter the word health in Keyword Number 1. And from here, we click Search. Click the little magnifying glass, that is, and then, Search. So you see now that the the Available Laws box has gotten a little bit smaller, meaning that there there are fewer rows now in that box.

And the reason that is, is because every statute that was previously in that Available Laws box that did not contain the word health inside of its body of text is now not being shown. So you can enter up to three keywords like that. So I could do 'health,' and then, say, I could enter 'genetics' into this second line.

The only thing is, you you have to do one word per box. Because if I were to enter 'genetics,' side by side with 'health' in the first Keyword box, what would happen is the Explorer would search for 'health genetics,' both of those words side by side, which is probably not what you were looking for. So let's go back to search.

So from here, let's say that we are happy now with this list of laws. We are interested in everything inside of this Available Laws box. The only problem now is that I don't have enough time to sit here and read all of these inside of the Explorer. So what you can do then is to click this Export to Excel button. And this shows you some instructions for what is really a a very simple process.

So if you were to hover over this box, click the ellipses, click Export Data, it will give you this pop up box, but you just have to click Export. You don't have to change anything here. And you see, now, it has initiated a download of data dot XLSX. So you can open this. And what is going to be inside of this Excel file – actually, I'm not sure. Are you seeing an Excel file, right now?

Unidentified Male: We can.

Unidentified Male: I can see.

Unidentified Female: I, yep.

Mike Wiley: Great, so what this is. All of those laws that were listed inside of your Available Laws box, the Explorer has now downloaded all of the information that it had into this Excel file. The the formatting is a little bit strange, but all the information is there. So if this column, column D is the legal text, so you can expand this, and show it.

The only downside to having all of this information in an Excel file like that is that that's a stagnant file now. We cannot go back and update that file for you, however, the Explorer will always remain up to date. So if you want to make sure you are seeing those latest updates, we highly recommend going back to the Explorer periodically. That is basically the process from start to finish.

The only thing now; you can restart the process by clicking this Reset Filters button. So you see the Available Laws box changed, and you're not seeing just California anymore because it has removed that filter. And you can start over.

One other thing I will point out, you've, we've seen now the About the Explorer tab, which was this landing page. We've seen this Search for Laws tab. There is one more which is labeled Feedback Form.

And if you go to this page, it will give you a very simple, and anonymous feedback form, which is if you believe that the Explorer is missing information, or you'd like to see additional legal topics covered in the Explorer, you can say that here. Or if you just have just general feedback for improving the Explorer, you can leave that in this second box.

Like I said, it's, it's anonymous but you're also welcome to leave your e-mail address if you would like. I will state, however though, this is not a place where you can submit a question for timely feedback.

So as I was discussing earlier, if you're someone who has pressing questions about, you need legal interpretations about a law that you read inside the Explorer, the Feedback form is not a a place for that. That is for, that is something that should probably be directed to the Office of General Counsel. That, for me is the full demonstration from start to finish of the Explorer.

So as we were saying, like, now is the time. Let's pause, and see if there are any questions that require me to have the interface up, and open. And so, I can quickly go back, and and show you, and clarify if there was anything; you might have missed me clicking on a button or something like that.

I'm I'm happy to to clarify anything here. And if not, then we can move onto our, kind of, fuller Q&A session that don't require me to show the interface.

Carrie Welton: Hey, Mike, this is Carrie.

Don Workman: One other question –

Carrie Welton: No, go ahead, Don.

Don Workman: – Is about the – one of the questions was about the addition of guidance from OGC. I mentioned a recent example about California. Could you show again where that would appear if it was added to the Explorer?

Mike Wiley: Yeah. Let's, let's go back to California. I don't know if there was a particular statute? But say, there was clarification about age of majority in California.

So you're reading this statute now, and if you selected it in the Available Laws box, you click the 'More info' button and that would appear in this Other Link column. So just like you have a statute link here, you might see an additional icon appear here to let you know that there is something worth reading.

Carrie Welton: Thanks for flagging that, Don. Most of the other questions we have are specific to to legal questions, interpretation, things like that. Our colleague, Matt, is on the line, but I think we may have to manually unmute him. So give us just one second, and he'll respond to those questions.

Mike Wiley: Parker, it, it's sounding like I should go ahead, and stop sharing my screen. Is there something –?

Parker Cunneen: We're gonna have to hand it – we're going to hand it over to Brandon, and he's going to bring up the the general questions for us.

Mike Wiley: Great, and I will stop.

Unidentified Female: Thanks, Parker.

Parker Cunneen: And I know, we we have a couple of panelists who are answering a variety of questions today. So whoever is just going to take it, if they could just read it out for the audience, that would be appreciated.

Mike Wiley: Great. Matthew, are you able to to speak now? I'm not sure if we got that figured out.

Matthew Razzano: Mike, can you hear me?

Mike Wiley: Yes.

Matthew Razzano: Okay, great. Alright, so if collaborative research occurs across state lines with research expertise, housed at different in VA sites, which state laws take precedence? That's a really tricky question that I I suspect on most occasions someone from OGC would need to step in, and and, sort of, clarify that situation.

That said, a a number of the state laws might, sort of, explain that you need to follow each, individual state law. But I think that that's, sort of, a fact specific question that will probably be very different from from each situation. So, sorry, I don't have a great answer there.

Don Workman: So so Matt, let me jump in. The, because with collaborative research, for instance, you're often obtaining informed consent on the same research study in Minneapolis as well as Boston. And so, the Minneapolis site would be following the Minneapolis state law, and Boston, it will be Massachusetts in terms of, for instance, the age of majority, and any particular requirements for informed consent.

The next question?

Matthew Razzano: Are state laws regarding embryonic stem cell research tagged in this database? So there, there are some, right now they're categorized within, I believe, it's, like, a genetic category within the tool. But it's not a standalone category as of now. So check there, if you're looking for those sorts of laws.

Molly Klote: Yeah, and just to be clear, VA only allows this type of research to be done following the NIH guidelines. So I would refer to them instead of trying to embark on your own exploration of this topic. The NIH has a, an entire site, and a 42-page application in order to get embryonic stem cells for any research projects.

Matthew Razzano: Will ORD's guidance relevant to research laws also be accessible to this tool? So similar to what Mike mentioned earlier, currently we're working with OGC to provide any guidance that they can. Like, similar to the first question, there are issues where OGC might be uncomfortable sharing, sort of, like, case by case guidance that they have issued for a particular situation, but working with them to include the instances where there's, like broad mandates, and decisions that have been made to include that in the, in the tool.

Are we able to get notifications for when a law or statute changes so we can update IRB forms or protocols in a timely fashion? So the information in the tool should be as close to, sort of, real-time as possible. It it gets updated on a regular basis. That said, it, there might be instances where you fill out, I suppose, a form, and then it sits for some period of time.

A recommendation would be to just go in and recheck the tool. Because then that you wouldn't necessarily receive a notification for when a law changes, but those updates will be consistently added into the tool. So it should all be up to date.

Are state laws regarding controlled substance use and required state licensure tagged in this database? There are some, they would be – I believe there's a drug-related research category in there, and then, I believe, a separate marijuana-specific research category within the tool. So I I would check there if you're looking for those sorts of issues.

Molly Klote: Yeah and and this is Molly Klote. So if there is something that you go into the database, and you think is missing, or you would like added, certainly, please bring that to our attention.

Matthew Razzano: Yeah I I believe – Mike and Carrie, correct me if I'm wrong. The feedback form is still with, attached in the tool itself, so that would be a great example of, you, you're looking for a particular area of law that you think would be useful. Please, include that information in the feedback form so that this constantly gets improved and built upon.

I just wonder that it will affect the data if we are collecting data differently depending on the state laws? But I suppose that this will have to be…. I'm sorry, I guess I'm not fully understanding the question there. I'm not sure if we can put the individual who added that on the mic?

Unidentified Male: So.

Molly Klote: Yeah, this doesn't seem like a question as much as a statement, right. And so if the state law were somehow, like, like one state law says, you can't return results. So so the goal of having the Research Law Explorer is that you would find these things out ahead of time.

Right, that when you're planning your study, you would be able to see that this is going to be an issue, and maybe we shouldn't do the study in that state. Or maybe we should look for a way around this, this particular law, or get the OGC decision on whether or not it applies to you. But but part of the the use of this is in planning out the research to start with.

Don Workman: Thanks, Molly. And I would just add to it the, the the writer of the question also makes a statement that collaboration with researchers in the IRB: The the tool is intended to be available for IRBs because IRBs are responsible for ensuring that legally effective informed consent, for instance, is being obtained. And so, therefore, they need to know what the legal parameters are within the state where informed consent is being obtained.

And to begin, there, there is an opportunity for IRB members to use it, for general counsel, certainly to use it, and advise us; but also, for those of us who do regulatory reviews to consider the implications. Over – the next question?

Parker Cunneen: I think that's the last one for the moment. I'm gonna give folks just a minute or two extra, see if there's any last ones.

Matthew Razzano: I'm sorry, is this a new question?

Don Workman: Yes.

Matthew Razzano: Yeah so similar to what we discussed earlier, working with OGC to add some of their relevant policies, and interpretations into the tool, the second part of this question, I think, again, is, it is unfortunately one of those situations that will probably depend situation to situation.

And for for complicated instances the best thing is always, or where you're not sure it's to go through the process to ask OGC. But and the, the the purpose of the tool is really to give you that really, really good starting place, help you understand 90% of the the easy stuff, and then filter the hard stuff to the the experts.

Don Workman: Thank, thanks, Matt. Though to go to the first part of the question, the tool is not for VA policies, or the interpretation of VA policies.

Matthew Razzano: Yes.

Don Workman: The tool is a collection of state laws, and, for instance, American Indian laws, territorial laws that are relevant to human subject and protection. So this is not a tool that you would use to look at VA policies for their interpretation.

Mike Wiley: I'll go ahead, jump on this one: Are there plans to make the tool more widely available, for example, to other federal agencies or the public? You've got it right that, right now, the Explorer is only available to those with an at VA dot gov e-mail address. But it was designed in such a way that it it could be expanded if necessary.

And I know that conversations have been had, but currently no set plan \_\_\_\_\_ [00:34:09] regulatory \_\_\_\_\_ [00:34:11].

Don Workman: Yeah so let me just reiterate that the tool is intended to be used only in the VA by VA employees, people with a VA e-mail address. And the VA, it's considering whether it could be expanded to other federal agencies or potential to the public down the road.

Matthew Razzano: What about laws related to mandatory reporting? So there are a number of mandatory reporting laws in the database. They they cover a variety of topics. So I think you'd have to take, kind of, a topical approach in how you search for them.

So for instance, I know there are some laws in there about communicable diseases, and required reporting related to that, and then a few other topics as well. But there's not like a standalone, mandatory reporting subsection of laws in the tool. You have to, sort of, search throughout.

Brandon Alexander: This appears to be the last question.

Mike Wiley: Right. Alright, we're at 3:05 p.m. Eastern, so I, I I think that that might be it. I'll give you about ten minutes back, but I just want to say thank you all so much for for coming to the webinar. And I really thank you for your interest in Explorer, right.

I'm really looking forward to to seeing how that's \_\_\_\_\_ [00:36:08] a valuable resource for, really, anybody who who intends to to use it at the VA. So thanks so much.

Parker Cunneen: Thank you, Mike, and and, Carrie, and all of our, Don, and all of our panelists there. Again, attendees, if you could, fill out the the post-webinar survey, we would appreciate it. And and thank you all for coming.

[END OF TAPE]