

Ms. Lili Portilla (NCATS) Oral History

Interviewed by Gabrielle Barr, Archivist, Office of NIH History and Stetten Museum, NIH

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G. Barr: Good afternoon. It is October 21st, 2020, and I have the pleasure of talking to Ms. Lily Portilla. Ms. Portilla is the director of the Office of Strategic Alliances at the National Center for Advancing Translational Sciences (NCATS). So, thank you so much for being with us. Our first question is: Can you please introduce the NCATS national COVID-19 cohort collaborative data enclave, and what aims NCATS hopes that this can accomplish?

L. Portilla: Right, but the N3T conclave, as we call it, is a collection of patients' records which do not identify the patients which you would be able, if you're someone that deals with informatics, to use the data set of all the different cases of people who were tested for COVID-19 or had COVID-19 to find and maybe answer questions about, for example, how some patients did with, and what were some comorbidities of individuals that were treated with a particular drugs. You know maybe a particular standard of care that was used in a hospital, maybe patients had a better result as a result of that intervention. So that's the idea of the enclave and so we are hosting the enclave.

Let me clarify that is data NCATS has received from about 65 institutions so far. The data gets cleaned up and then, if you're a researcher and you want to use the data to answer some questions around COVID-19, you would put in what data access agreement with us—data use agreement—and with your institution so that agreement is good for your entire institution. Anybody in your institution could tap into the enclave. But before you get access to the data you have to submit what's called the data use request, and that data use request talks about who you are, what institution you're affiliated with, what is the title of the project you want to do, what's the proposal, what question do you want to get answered and depending and also requesting what level of data you need and a justification as to why you need that level of data.

So, more information, like a limited data set, will require more hoop jumping. We want to make sure that there's an IRB approval and things like that, such as that you've gotten proper training to access the data so there would be certain requirements that are needed based on the level of data and there is a data use committee (DAC) that is run by NCATS, along with other NIH IC representatives, as well who will approve these requests and determine whether, yes indeed, that individual can get access to that level of data. Then the DAC facilitates that piece and do the approvals. So that's how that whole thing works right now.

G. Barr: So, you and your team have been very involved in drafting these data transfer and use agreements for researchers. Can you speak a little bit about what that entails? You mentioned a little bit and sort of what the process has been like for you in terms of drafting and overseeing.

L. Portilla: Right, so yeah, our office has the function of putting together all the agreements for NCATS so that's why we were tapped to do this particular task and that's why we got involved and with the establishment of the enclave. You know again we're hosting the data, so they needed our input and expertise inputting these agreements together. You know, in creating these agreements you definitely want to make sure that people understand what the limitations are for using the data, what the expectations are, what we expect of them as researchers adhering to certain codes of conduct that are

related to the enclave. Our role is to put together an agreement that kind of spells what the terms and conditions are. But we want to make the enclave as accessible as possible so we don't want to make it overburdensome either from the perspective of making requirements that we know, for example, universities would never be able to agree to.

I think that's some of the expertise that we bring in since we know how to craft such agreements together and this particular agreement was one that started off in a discussion with OGC who was working on a similar type of arrangement for another COVID-19 related project and we started with that as our basis of how to put it together because, of course, it had NIH OGC approval. I mean that's a huge time saver, so we used that as a place to start. Then we also went and looked at other data use agreements across various NIH programs, to see what they were doing and how we would have to arrange ours to address the way that the enclave was going to be governed. So that process took a while and, you know, we got input from many including legal, policy, even the IT people. It was truly a huge effort from the perspective that many groups were involved in putting those agreements together.

G. Barr: You don't always realize that you are the person that sort of acted as the go-between for all these different people with different areas of expertise in putting the agreement together.

L. Portilla: That was kind of our task to make that happen so we would consult with our program officials, our policy officials, and sometimes some of these issues and requirements require their input because they know, for example, how certain policy issues may affect some of them ask that we have in the agreement so we want to make sure that they're on board. Same thing with IT. You know, how are we going to treat the data and we need to know that ahead of time because we don't want to put requirements that we know that our IT would never be able to manage.

Another thing we actually did before we launched it is that we went to a couple of institutions that we knew were going to be working with the enclave and said to give us feedback on the draft. We even provided it in draft format to people who would be signing it to get a sense of whether it was something they could agree to. We did a lot of community outreach to figure out whether indeed this agreement was going to be workable. I am proud of the work we did there because, I think we sought a lot of opinions to get this final product.

G. Barr: Do you normally do this level of outreach and consultation with other projects that you do, or did you feel extra pressure with this more visible COVID-19 project?

L. Portilla: Well, of course, I think with the visibility of COVID-19 the visibility of COVID-19 and the nature of the data we have in the enclave. It was really important because we don't want to create a resource that no one can use because you've made it so burdensome. Right, I do think that we sought a fair amount of approval out there maybe more than usual but I think when you're putting together an agreement that involves perhaps universities signing it, it's always good to get a reality check on whether you've put something in there that they could agree to. So for me personally through the years and with the contacts that I've developed and doing what I've been doing for many, many years at NIH, when I have those situations, I have go-to people in various universities that I know, colleagues that I can say, and get a reality check on, what do you think of this agreement; would you sign it? What do you see as problems? I think when you're putting together big programs like the N3C Enclave you can't put the agreements in a vacuum. You really should be trying to get as much input as possible because you want the resource to be used as much as possible.

G. Barr: Definitely. So how did you balance in this agreement a lot of competing interests you mentioned? But you know there are issues such as ease of use, security, patient privacy, intellectual privacy—they're all very, very important things.

L. Portilla: And that the agreement took a while to put in place for that very reason was that we wanted to seek input from all these groups and make sure that we could adhere by making sure that we weren't asking someone to do something that we could not follow up on or agreed to do something that we could never agree ourselves. So, I think that you know we could have just put a plain old data use agreement together instead and, you know, do a find and replace changes what we've used it for last time and used it for the enclave, but because of the fact that the pandemic is ongoing that we want as many people to use this. It's important that we put something together in terms of the agreements that really that we know people are going to sign. The fact that 65 institutions signed the data transfer agreement—that's the agreement to transfer data into the enclave—and requested no change, said we can sign as is, and that over a hundred data use agreements have been signed, is kind of a testament to the process of like putting in the work up front really paid off on the back end.

G. Barr: That's really great. Are most of the institutes within the United States? Are there also institutions who have signed from abroad?

L. Portilla: At the moment the majority are U.S. universities; however, there are some for-profit companies who want to use the data now. I can't tell you what for because I haven't seen the follow-up data use requests, but there are non-profit organizations that are not affiliated with universities that have also requested data and there may be a few foreign entities have plans to request the data too. And I'm saying data because I don't know what level yet, but again that their request has to be reviewed by the data use committee and there may be instances where certain kinds of data cannot be given to, for example, foreign entities. We made a decision that we could not give the limited data sets to foreign entities, so we know that if that data request comes in we're going to have to deny it and tell them what level they want to use. Citizen scientists, individuals who kind of want to go in and play with the enclave, can do that but they're only going to be able to access what's called synthetic data which is stripped of any personal identifiers. But you know that the citizen scientists could actually check out the enclave as well, too, but they're going to be restricted on what they can do, based on some policy decisions that we made about how, who and how the data was going to be accessed.

G. Barr: How do you think that your particular set of skills and educational and professional background—you've been working with this sort of thing for a while now—has equipped you to handle this particular initiative?

L. Portilla: I think the agreement space is a space that I'm very comfortable working in because I've been doing it for a long time at the NIH. I think the thing that was a learning experience for me was the fact that it related to a pandemic right; I mean you want to move as fast as you can but you know it's that analogy of building the plane while you're flying it. In some respects, I think in the early days of putting the enclave together, that's what we were doing. We were kind of building it as we go and that was a very interesting experience for me because I can't say that I can point to too many things in my career where I've come in and tried to put agreement around it. It's usually something that's been well established right or a research collaboration that you want to get done, this is what we want to do, we need agreements. we need your expertise. Myself and other people in my office were lending that expertise where we could and you know we learned something too, as well as my colleagues on the

other side of the table who we were all working together to get these agreements in place. They learned something as well from us, so I think it was a great way to do some information sharing and work with parts of the organization that maybe I haven't really worked with before is good, other challenges that you've encountered so far—I mean I think it's doing that was good and it was all toward a common cause which is even better. Right?

G. Barr: Definitely. Was that your biggest challenge that you're doing this in the midst or were there in the middle of all this and, you know, and this still is the case? This isn't the only COVID-19 related project that's going on at the NIH.

L. Portilla: Right, there are many, many projects going on so I think that's another unique thing here is that it was all hands on deck with having to deal with COVID-19 at NIH and it still is even now, well into many months into the pandemic. It's things that are relied upon. I don't think that the intensity has changed much. I think it's still there and but again, it's refreshing that everyone has risen to the occasion here and continues to do that. I'm happy and I'm proud of the fact that I'm able to contribute with my very unique skill set.

G. Barr: Right, that's really great. Well, you're part of a larger office. About how many people in your office were working on these data use agreements with you and what were their particular areas of expertise?

L. Portilla: So, I was doing a fair amount of work and then I brought in a colleague who is someone that I've trained. He's been working with me for many, many years and I brought him in because not only is he great on agreements he puts together, but also he understands what a good agreement looks like from the NIH perspective. He's super talented when it comes to business processes. A lot of this was understanding what the business processes of the enclave were going to be, so that we could frame our agreement around that. So, I think he also added a ton of value around how these processes of making a request were going to work and how that related to some of the steps that someone needed to take to get an agreement signed. So truthfully, it's just me and him from my office. I have a small office—it's about seven people including myself, but I had other people working on other parts of COVID-19-related projects. We were working with one of the OWS ACTIV clinical trials putting together agreements for that, but for N3C it was me and my colleague, Chris Dillon, who have been intimately involved in the establishment of those agreements for the enclave.

G. Barr: Yeah, that's interesting. What would be your advice to others on how to handle very complex multi-party and public-private collaborations such as the N3C data?

L. Portilla: I think one of the philosophy or one of our tenets at NCATS is team science. And in in-putting together a large multi-faceted multi-institutional party agreement or initiative you've really got to have a team around you. It can't be individual people working together; there's got to be a lot of collaboration and seeking input and expertise. Maybe you have to go outside of your institution, so we do team science at NCATS and this is no different what we did in putting the enclave together. I think one of the unique features about it is that you know they value what everyone does and brings to the table and the fact that my office was able to bring value and be around the table contributing to this project—I mean my office doesn't just talk the talk, we walk the talk.

G. Barr: Right, that's really great, so in addition to the N3C data you said that your office worked on other code data agreements. Can you briefly describe what were some of them?

L. Portilla: Yeah, so our intramural group was doing a lot of COVID-19 related research projects, so we worked a lot in the early days of the pandemic—I think in the first couple of months we put about 20 separate research collaboration agreements in place to deal with projects that people wanted to work on with other collaborators having to do with COVID-19. So, we were doing that while we were doing the enclave and then we got involved in putting the ACTIV1 clinical trial agreements in place and that's a multi. It has various drugs that are being brought in and that required us negotiating clinical trial agreements with four separate pharma [pharmaceutical companies] and we did it in a very short period of time. On top of that we're still doing our day jobs. So, this year we're going to have an astronomical amount of work and agreements to show the fact that we have been very reactive to what's going on with COVID-19. So, my office, because of what we do, kind of is luckily being able to touch all these different projects and learn about them and have some impact as well, too. We're not doing the science but we're just giving the framework for the science to happen.

G. Barr: Well, that's very important and people often don't realize that it's really a first step in order to do some of these trials and tests. So, another one of my questions, I think you said that you're doing your day job in addition to all these COVID-19 agreements. What has been like to juggle some of your everyday responsibilities with your COVID-19 work and do you have any tips and tricks for others who are balancing a lot of different balls in the air right now?

L. Portilla: Yeah, I look at co-workers that have young children and I don't know how they're doing it. I think that to me is something as a supervisor that I'm very cognizant of is that, aside from the fact that you're doing just a ton of work at home. For me personally the days just seem to run into each other. Sometimes I'm working way after my tour of duty just because I know that something needs to get done and on top of that you know you got to run. I also have a family that I need to deal with and I actually have my elderly mom who lives with me right now, so I think it's really challenging trying to manage all that other stuff and for me my job is kind of my escape right now because I'm really feeling I'm contributing and I'm really doing something valuable to address the pandemic.

I love working at NIH; I've been at NIH for 29 years. It has been a long time, but I've never felt so connected to the organization like I have in the last six months. I feel that what I'm doing has a direct correlation to trying to address something in the pandemic and I think the folks that work with me also feel that way, too. But one of the things I do miss about my going into the offices is talking to my colleagues and my staff. Since I have an open-door policy, I would have people strolling in and out pretty much all day. But that's how I got to know what was going on and to me that's the thing that I miss the most and I feel like we might be missing out on some great ideas, because impromptu conversations with colleagues. So, I'm trying to figure out how to make those impromptu conversations happen in a teleworking situation. I'm thinking about having office hours during certain parts of the day. When you know you want to come and talk to me, you need to just sign up and come in and we'll have a conversation. It doesn't have to be work related; it could be you just want to talk, you know, have a conversation.

I suspect that we're going to be doing this for a while longer. I think it's funny how as humans we get used to something and I feel now I'm getting very used to this, but, yeah, clearly there are things that

you miss out, going into the office and talking to people. Going to do something fun after work with the colleagues, that's stuff that we're all aching to do but we just can't.

G. Barr: Yes, that's true. Have there been any personal opportunities for you working from home?

L. Portilla: Yeah, I mean I've certainly gotten a glimpse of a lot of things about my home. I don't know if this is what you meant but you know being here at home, I look at things. Oh my gosh, that needs to get fixed. So, I feel like I have a direct line to Home Depot because that's where I seem to spend most of my weekends trying to fix something or change something in the house. So being at home I've just noticed things that I've never noticed before, so I've become a do-it-yourselfer. That's another thing that's different, trying to keep myself entertained as much as I can. Yeah, it's challenging but you know my husband also works for NIH for us, it's been super gratifying, just being able to contribute during this time.

G. Barr: Yeah, we called animal control as we had squirrels in our attic, and they said that they've never been busier since people have been home, they get all these calls.

L. Portilla: My front yard never looked as good as it does now.

G. Barr: Right, I know what you're talking about. So very interesting. Well, is there one thing that you have learned about yourself during the pandemic?

L. Portilla: Yeah, I kind of alluded to it earlier. I've figured out that I'm a lot more adaptable than I thought I was because like I said, when this whole thing started I was like, oh my god, you can't do anything, but I think I'm getting used to it. We go out, you do stuff—you talk to your colleagues, you have virtual get-togethers. I think we've just adapted to trying to stay connected as best we can. You know it's not like the real deal, but I'm surprised at how adaptable I've gotten in the midst of what's going on with the pandemic.

G. Barr: Yeah, I think we all can say that. Is there anything else you would want to share as a person who works for NIH for many years but also as a person who's dealing with a lot of different aspects of COVID-19 as a person?

L. Portilla: I feel like, let's see how to frame this, so for me I guess the frustrating thing is that I feel like I'm doing what I can to address the pandemic. It's funny when I talk to certain family members in different parts of the country, I can see a disconnect—I see COVID-19 as a “hair on fire” situation. I talk to other people in my family and I don't get that sense of urgency. That really bugs me, but I think that's one of the things about working at NIH that you get to see really the health impact of what is going on with COVID-19.

And in the same vein I have friends calling me asking me questions, like, hey, “do you think I should send my kid back to school?” and I'm not equipped to answer that but I think they think just because I work at NIH, they think I am some health expert. I can't stress this enough, for me it's been so gratifying being here when all this is going on and one of these days when people look back and see what we did, I think they're going to be surprised and say NIH did so much and so quickly and rose to the occasion. I'd like to think that that's what folks are going to look at when they might read this, see my picture and ask “What did she do during the COVID-19 pandemic?”

G. Barr: Thank you very much for your time and I wish you and your team the best in all of your work and I wish you and your family the best and that you continue to stay safe. Thank you.

L. Portilla: And same to you and I appreciate the opportunity to tell everybody what NCATS has been doing.