Dr. Stephanie Devaney
All of Us
Oral History

The All of Us Research Program is an ambitious effort to gather health data from one million or more people living in the United States to accelerate research that may improve health. All of Us is working with participants across the country, collecting many types of information over time, and building a database that many researchers can use. This new model could shape how people do research in the future. All of Us will share lessons about what works well with other research programs around the world. The program is supported and overseen by the National Institutes of Health (NIH) and is the result of NIH's Precision Medicine Initiative Working Group of the Advisory Committee to the Director, which concluded its work in 2015.

Condon: I'm Aaron Condon, it is Friday, October 13, 2023, and I'm joined by Dr. Stephanie Devaney, who is the chief operating officer of the All of Us Research Program. Today, I'm going to conduct an interview to explore the origin of the All of Us Research Program, and document it as part of an oral history project for the Office of NIH History and Stetten Museum.

How are you today, Stephanie?

Devaney: I am great. Thank you very much, Aaron, how are you?

Condon: Okay. To begin, can you give us a little bit about your background and your history?

Devaney: Sure. It's not that long, so I won't take up too much time with it. I went to undergrad at Ohio State, and I fell in love with science. I sort of followed the path and accepted a position at GW [George Washington University] in their Ph.D. program, graduated with my Ph.D. in biomedical research, but also along the way, learned that I wasn't really that interested in bench work. I loved science, but I didn't want to go the traditional route of professor and constantly seeking funding for what, for me, was too isolating of a job. I had done an internship in science policy while I was getting my Ph.D., and I loved it. It really sort of pushed me into the policy side of things. I ended up at NIH working in the Office of the Director with Francis Collins, right when he had started as NIH Director under the Obama Administration as Obama's pick, and then learned a lot about scientific administration and leadership, and how to execute [policy] in a large agency at that time. That gave me good preparation for ultimately coming to All of Us.

After working at the NIH and in the immediate Office of the Director, dealing with kind of a political environment there, or at least a fast-moving environment, I got the opportunity to put my hat in the ring to run the Precision Medicine Initiative [PMI] on behalf of President Obama. We can talk more about that and the

origin further along in this interview, but long story short, I got the job. I went down to the White House for the last 18 or 20 months of his presidency and helped to lead, and get off the ground, the Precision Medicine Initiative, of which ultimately as one component of it is the All of Us Research Program. And then at election time, when the administration turned over, I took the job here at All of Us. I have been here with the program since very close to the beginning. The FY 16 funds were the beginning of the program, but there was a lot of the build that I was not here for.

Condon: Okay, that must have been fascinating, working downtown. Can you expand a little bit on what that was like, during the initial phases of the Precision Medicine Initiative?

Devaney: I'd be delighted to. President Obama, originally when he was a senator, was really interested in this idea of personalized medicine. I think he even put forward a personalized medicine bill, and it would be easy to track some of the discussions on the floor of the Senate around that bill, because that was around 2006. I know he was really championing that and trying to push it through. Fast forward, he gets elected as president, has this really big, strong priority of health care, and the ACA [Affordable Care Act] comes about and all of the health care policy that he really focused on at the same time, he was so focused on science and technology, and put together the USDS [United States Digital Service] and some of those other scientific strengths within the White House, and got re-inspired by the idea of precision medicine. If we've got such significant computing power, and we've got electronic health records, and we've got people who want to be part of research, and we have better computing, better tools, and we've got researchers across this country [who] are really well resourced, why shouldn't we be able to do a better job with healthcare delivery and be more specific to the person? I am now speculating, but in my mind, I think the White House emphasis on policy and science is very complimentary, also acknowledging that when you put in place scientific discovery, and things come out of that, that lasts. Whereas policy can be overturned by an upcoming administration. The brilliance of putting into place a scientific component around his health interests was that anything that this program develops is lasting, and if we can communicate it, well, those findings can be built upon and ideally we can have a real impact in health. So, that's where it all came about with Obama when I went downtown.

President Obama's team reached out to a number of agencies, specifically starting with the Department of Health and Human Services (HHS), and HHS then pulled in the VA [Veterans' Administration] and DOD [Department of Defense]. So, it became a request across departments and agencies to put together essentially a plan. The President was essentially like: If I wanted to do something in precision medicine or personalized medicine, what would that, what could that, look like? And of course, as you know, the White House doesn't have resources in the same way that the departments and agencies do, so that they're reliant on them [to answer]: Here's the policy priority, or here's the scientific priority, what can the departments do? What can the executive arm do to make that happen?

And so a small group of us at NIH led by Francis Collins, who had had this idea for many years, who back in 2004, I think, he wrote a paper about this idea of launching a million person cohort with mixing genomic data and electronic health record data and all the different types of data that we are collecting on individuals. He had that

idea back in 2004, but it was cost prohibitive, because the genome cost a billion dollars around the turn of the century. We would not have been able to sustain it cost wise. Collins got excited by Obama's attention on this [because it had] been a real vision of his. As the person who oversaw the sequencing of the human genome, I think he really had this as a vision for a long time. Then out of his immediate office, we led a big part of that idea. We knew that we had to put this into a memo; let's create what we think could be a real, impactful scientific initiative that we could present to the President. Then if it gets that support of a broader, cross-governmental initiative, hopefully, we can get funding and support for it.

We put together the proposal of All of Us , and I was the one doing the writing, listening to all of these experts from across NIH, including Eric Green [National Human Genome Research Institute Director], and Gary Gibbons [National Heart, Lung, and Blood Institute Director], and some of the other IC directors, and office leaders from the OD [National Institutes of Health Office of the Director]. I absorbed all of that and did a lot of the writing to pull that memo together, which then got housed with a proposal from the FDA and from the Office of the National Coordinator, and from the Office for Civil Rights, some of the groups that oversee electronic health record regulations on these ideas of how we could do this in a cross agency way. I compiled all of that, and it went into a memo for the President in 2014, probably very early 2015. Maybe you've seen it in the State of the Union address by Obama in which he said, “I want to launch this Precision Medicine Initiative.” We had been working on that memo behind the scenes, and then that became the announcement of it.

Once we knew he was in, and he really liked the proposals, it really came down to, “Okay, now somebody has to organize this.” Because, as you and I know, agencies are not necessarily going to organize themselves on what has to come from the White House and organize it. One of the things that I thought was so interesting and important about the Precision Medicine Initiative is that it ended up [that] Obama assigned one of his very direct advisors to oversee the initiative. And this is a gentleman named Brian Deese, who had been with the White House for a while in a very small circle of folks that reported directly to the president; he was also overseeing climate. It was pretty apparent in the positioning because the White House is made up of that immediate office, the Chief of Staff's office, which is where my position was, as well as longer term offices like OMB [Office of Management and Budget] and OSTP [Office of Science and Technology Policy] [These offices are not in the Chief of Staff’s office]. Some of these offices don't change as often with the politics. The importance of that was it showed that President Obama himself, while he didn't have time to devote to the running of the thing, was so invested in both climate science and precision medicine research and science, that he put those two initiatives inside of his immediate office with one of his most effective advisors. When I accepted the position, I reported directly to Brian Deese. That meant that I was really close to the vision of the President because I was working directly and closely with the person that was meeting with the president every day. That was really important, I think, to the success of the overall initiative.

I worked with a number of amazing colleagues in the Office of Science and Technology Policy, which is a larger, 100+ folks, I don't know what the number is now, but that's a very large office in the White House. I worked with a lot of folks from that office, as well as the Domestic Policy Council and the Economic Council and some of the other offices. We were able to do a lot and help ensure that the full initiative was being stood up soundly, because of that really strong support from the President. We spent about a year or so planning for the kind of stand up of the initiative. That was when I went down and took that position in March of 2015. Then in

September of 2015, the All of Us Research Program, Francis, and some other folks at the NIH who he had asked to take this on, started up a working group under the Advisory Committee to the [Director] NIH structure, and that was called the Precision Medicine Initiative Working Group.

I think there's all sorts of documents online that you can look through in that, but they essentially developed the blueprint for the program in this report that was then delivered to the NIH Director through this working group. That blueprint outlined the different premises of the program: how the cohort must be diverse, and we must put extra investment into the diversity of the US; and we must have broad and open data sharing because too many institutions silo their data; and we must have participants as partners and return value to them, because we really wanted to make sure we were doing research differently. [Research] had just kind of organically evolved in a not so participant friendly way over the years [and] we wanted to ensure that that was all done differently, and this report really encapsulated all of that, so as the program was built, these should be the fundamental aspects of it. Then Congress gave us our first funding; there was a lot of work both at the White House and HHS on the Hill that encouraged the support of the Precision Medicine Initiative with backed funding. We were successful and we got funding in FY16. The funding has gone up since with a steady show of support from Congress that then launched the whole build of the program. I can talk about any aspects of that that you want.

Condon**:** Well, that's great so far. I was able to get my hands on all of the material that we have available to us here. I read everything, but your descriptions of what happened before we had those materials makes it really helpful to understand. Thank you for that. Let's discuss, if you wouldn't mind, your role as you transitioned into a member of the program, the PMI program, I think it was called the beginning.

Devaney: You mean, Aaron, when I moved from NIH and took the position at the White House?

Condon: When you returned from the White House, and you came here to start working on the initiative. What was your role at that time?

Devaney: Yeah, great. A couple of weeks after the election, I left the White House because that office is fully vacated. The Office of the Chief of Staff goes away, so folks were starting to leave. I came back to NIH and at the time, Eric Dishman was the director, the inaugural director, of the All of Us Research Program, and he and I had worked together really closely while I was downtown. We had gotten to know each other really well, and he offered me the position of deputy director. So essentially being his second and I could represent him—and also we ended up splitting portfolios that way, too. I think it was a real complementary relationship because Eric came in with this incredible experience from industry, which is a different model from how the government works, I don't have to tell you, and so he had this perspective of “We have customers”, so to speak. We have stakeholders that we need to serve. The way that folks in the private sector think is in terms of let's make sure that there's a good design. Let's make sure we're thinking about the needs of the people we're working with.

[It's] not different from the government, but the way they go about it and the sort of systematic processes they use are not all that frequently found in government. He brought all of that to the table. And then, of course, I had all of this government experience. I knew a lot about science policy as in academic study, but also the various agencies and departments across the government that do policy and that the government is the only part of our country where policy can be done. I had a really good understanding of the different sides of policy within the government, and who does what, and the stances of different agencies and their interest in supporting precision medicine. I brought that experience and then also an understanding of the institutes and centers here at NIH. While I have never been in an institute or center, the time that I spent in Building One really did give me a broad view of the agency and an understanding of how different the institutes and centers are from each other, and how they work together well, and what happens when they don't, and all of that perspective. Under my portfolio was the pot all of the policy pieces, establishing the Institutional Review Board for the program and all of those regulatory requirements that would keep us running in an ethical and safe way. And interactions with the institutes and centers and more of that, like, government approach. In that way Eric and I really complemented each other, and it was a way for us to split our portfolio while also we could back each other up. That was my role when I first came here. It was around December 2016.

Condon: Okay, great. Then also in 2016, I think the name changed from Precision Medicine Initiative to the All of Us Research Program. Why did it change?

Devaney: Yes, great question. That would be a good thing to talk to our communications team about too at some point, if you get a chance, because while I was downtown, they changed the name. I am aware of some of the thinking that went into that but was not here for any of the mechanics of it. I do know that it was a really good opportunity for the program to show that the values we established from the beginning, were actually going to be the values that rooted into our decisions. When we decided that this cohort program is going to be different, we're not going to just slurp up a bunch of data from people and never talk to them, we're going to return value to people, we want them to be partners in this, we want to understand what works and doesn't work so we can make modifications over time. That relationship required a sense of trust. It's not a branding issue, but there is an importance to how you represent yourself, right? A program that's named the Precision Medicine Initiative Cohort Program is just not intuitive to people and doesn't really reach out with any sense of understanding of what we're trying to do. They launched an effort to think through the name of the program, like, what would we want our name to convey to people, knowing that we're not working on a government only operation here, we're trying to build a national cohort of individuals. They worked with their contractor, the awardee, Wondros, who had come on board with FY16 funds as an engagement and communications partner, I think. They did some user testing on what does a cohort program mean, and did some testing on different wording, and landed on All of Us. That's when we and then the community, in collaboration with our communications team, ultimately made the final decision, worked on the brand in the taglines, and from that point on our name has been All of Us.

Condon: Okay. Did you notice any changes in the community or in the industry after the adoption of the new name, or was it kind of just the same thing?

Devaney: That's such a good question. I can give you a gut feeling on that. I have no evidence to back this up whatsoever, but my gut feeling is there was a pretty significant change. I think that the name itself, even though it's just a title, the name itself conveys a sense of community and what we're trying to do in such a more direct way. Given the original kind of wonky working group title, that I think it allowed us to even show the communities that we're actually trying to build something for All of Us. I do actually think it changed the tone of the conversations. People still know that it's a government program, that we've done everything we can to show that while the government is funding it, and it's a public investment, it's really a program that is made up of partners from across the country and then ultimately, the participants. We wanted it to have that kind of a feel to it.

Condon: Thank you. You mentioned that Dr. Collins had first concepted the idea of one million participants. That is one great goal of the program that a lot of folks know. Another goal that not so many people know is that all the information, all the data that we're gathering, is basically free for institutions across the United States: research institutions, universities, and this is one of the goals that I love. Being at NIH for a while, I understand what it takes to recruit participants and the cost that entails and the resources it entails. How did the data sharing element begin? You spoke a little bit about that with Dr. Collins' paper, but can you expand on that a little bit?

Devaney: I can. I remember when we were thinking through all of this even before the ACD [Advisory Council to the Director] Working Group was established, and we were kind of a smaller group within the NIH working on the memo for the President, which outlined the program in enough depth—not as much depth as the original working group report did—but in enough depth to explain the priorities of the program. As we were thinking through this, the connection between participants as partners, and broad and open data sharing [became apparent]. Because we believe through various research that has been done with participants [the core questions are:] What is it that you want in a research study? What would make you compelled to join a research study based on those conversations? And just an understanding of where the ethos was going. We knew that participants were inclined and excited to join a program where they knew all sorts of bright minds from across the country would have access to the data and be able to use it to answer questions that we don't have answers to, instead of the model where a certain institution, certain hospitals, certain academic center, holds the data, and frankly hoards the data, and makes it available only to their employees. We believed that that was an important value proposition back to participants, that the data you provide will be open to communities of research from across the country, from all different types of institutions, including researchers that come from your communities, if they want access. We've invested some into it, but I think there is a real opportunity to continue to invest in asking participants what kinds of questions they'd like to have answered, and having researchers who are ready to come in and do that research using the data. Knowing that all communities wouldn't, however you define your community, whether it's, you know, hyperlocal to your neighborhood, or it's a national community of people with important health concerns, and they're different. They probably have ideas on what they wish researchers were asking of the data that they've contributed to. From our perspective, that

was always a really important loop, and that if this program, if it does anything different, should make sure that we're democratizing the use of the data since it was donated by people and make sure that we're building capacity and researchers across the country to both do novel research and also work with participants and understand what they want and do that novel research. That was all kind of that was all part of it from the beginning.

Condon: Can you describe a really interesting study if you have one in mind? If you don't, it's okay. One that is being done or has been done in the past few years with the data?

Devaney: Yeah, Aaron, that's such a good question. I think you would get a great answer on this from Geoff [Geoff Ginsburg, *All of Us* Chief Medical and Science Officer] or Josh or some of the folks that think about the science so much. I end up spending most of my time looking at who are the researchers that are using the data. How many are there? What's the cost? How much of the compute costs that we give out are they using? Are they having problems accessing the data? More of the operational stuff is what I pay attention to. But what I will say is that at this point in time, only a little over three years after we launched our very first data set, we have more than 7000 researchers using the data. There's all of this work that's ongoing. One of the other things I love about this program so much is you can go onto our website, and you can look at all of the ongoing projects with a description written by the researcher. We know all of the uses and all the questions that are being asked, and anybody in the public can know that at any given time, and it's real time. I love that about this program. And we're now also starting to see publications come out. There's over 200 publications citing the use of All of Us Research Program. Somebody could do a really interesting analysis of what are the questions that are being published. [About] the individual science, you will get a much better answer from some of the other folks [in our] our program.

Condon: That is great. How about privacy? Privacy is always concerning when gathering and storing study participant health data. What are the main ethical considerations of healthcare providers having access to data that could be considered clinically actionable when providing treatment for unrelated matters?

Devaney: On the privacy side, I will tell you by way of background as some interesting history for the All of Us Research Program, when the Senate and the House were working on the Cures Act, this was at the same time that we were designing the Precision Medicine Initiative. It was all part of the administration and Congress working together on this. The Cures Act, which ultimately also authorized funding for the program, had a bunch of provisions within it that were designed by the Congress and the staff there to support some of the work that they knew would have to come out of an initiative like this; for example, there's a provision within the Cures Act about certificates of confidentiality, which you may or may not know something about. This is a really important provision, because as we were designing the program, as we were forming any effort to engage a diverse set of participants across the country, you are going to run into concerns about privacy of data, right? Who's holding the data? How are you protecting it? Is this going to harm me? We heard that from all of the different

communities that we talked to for different reasons. The certificates of confidentiality made it immediately illegal for a researcher to hand over data on participants under any legal subpoena. So one of the concerns we heard from participants was, “Great, we trust that the researchers are going to manage the data under their data use agreements appropriately and that the program is going to watch that, but what will you do if you get a subpoena for law enforcement? Is all of our data just then going to be turned over for use by authorities?” The Cures Act, it gave us much more strength in this space because now if the program gets a subpoena of any sort, we are not legally allowed to hand over participant-level data. If the program did, which it would not, but if a researcher did hand over data on our participants, it is inadmissible in court. That provision provided both the upfront legality but also handled it on the back end to where it would not actually be able to be used as evidence. That was so important for our program. We have reminded and explained that to participants so many times, not just as a messaging around privacy, but as a real tool that we have in the program to protect the data. That's one thing I wanted to say about privacy, and there were a couple other provisions in the Cures Act that helped us too. This was the importance of doing program development and policy development at the same time when you're designing an initiative this big. The second part of your question was on actionable data.

Condon: What are the main ethical considerations of healthcare providers having access to data that could be considered clinically actionable when providing treatment for unrelated matters?

Devaney: I think the question you're asking is: If researchers have a whole bunch of data that they're doing research on, or a clinician who's doing research, and they learned something actionable about one of the individuals within the cohort, what is their responsibility? Right? In our program we've been really clear about certain types of information that we will return to participants, notably genetic information. We are now returning actionable health related genetic results to participants if they want it individually. That information was developed in the clinical labs where we know the clinical assay that's being used to test those different points across the genome are valid and sound. We have an investigational device exemption from the Food and Drug Administration to support that, so we know that this is sound and accurate information. Therefore, we feel very competent and comfortable returning that to individual participants who didn't come to the program for our clinical tests, they came to the program to engage in research, right, so for returning clinical information to them, it's important to us that we know that that information is accurate. We understand the clinical implications of that data. We can explain it to people. This is why we awarded the genetic counseling resource—to make sure that we had medical professionals who could actually report to someone that they might have a cancer susceptibility, mutation, or some other actionable health outcome. That’s us who collect the data and curate the data and make it available to researchers, when a secondary researcher is accessing the data through our platform, they're signing a data use code of conduct and their institution has signed a data use research agreement, both of which remind the researcher that they are under no circumstances allowed to re-identify an individual within the data set. So that data is de-identified. We have privacy experts in many different organizations, but especially in our tech platform, who are modeling this and making sure that the folks are not readily identifiable, but we also prohibit researchers from attempting to re-identify and there are enforcement actions that we will take. The nice thing about having the data in the cloud and a researcher accessing it that way is we can cut off their access at any time if we can tell that they're pulling data out or trying to re-identify

someone. That protects clinicians from looking in the data for clinically actionable items and being able to report to someone outside of the healthcare space. That's not something that we want to see happen with our data, and our participants would not expect that, and so we protect them from that. Does that make sense?

Condon: It does make perfect sense. Thank you. You went into the Cures Act support a little bit, and I've been interested about that. You mentioned some of the ways that we're affected by Cures funding. What are the other connections really between the Cures Act and the All of Us Research Program?

Devaney: The Cures Act set up an authorization for funding in this sort of weird way over 10 years. I believe it was oil offsets; there was some way in which Congress got the money that they could make available, assuming appropriators appropriate it, but that was the funding aspect of Cures. And it was really important because it's a show of support and financial matching to help us build the program. There were very many other provisions within the Cures Act, some of which were reporting requirements for the program. And some of which, as I mentioned, on the certificates of confidentiality, were really important policy aspects of the program, including some strengthening of FOIA [Freedom of Information Act] and some of the necessary protections under FOIA to make sure that we're not having to give away participant data under a FOIA request. There was some important work there about the Paperwork Reduction Act, which helped ensure that some of the operational things we were doing wouldn't be involved there. And there were a number of other provisions of which I can't remember right now, but the Cures Act is readable and it's understandable, and I think they really put together a nice package of policies that supported the program.

Condon: Okay. All right. We kind of got off my list of questions a while ago, talking about all of this and that's great! I think this topic brings us to a conclusion. I do appreciate your time. Do you have anything else you want to share? You have anything else you want to talk about?

Devaney: I don't think so. Aaron, that was a really good and comprehensive conversation. I hope that I was helpful.

Condon: Okay, that's great. Thank you very much.