

## RECOVERLive Series: What is the RECOVER Initiative?

November 30, 2021

12:00 – 12:30 PM EDT

### **Dr. Josh Fessel**

Time: 02:14 – 03:05

Hello and good morning, good afternoon, or good evening. Whatever it is, wherever you are. Thank you all for joining us for the RECOVER COVID live series. I'm Dr. Josh Fessel. I'm a medical officer at the NIH, and I'm working as part of the NIH executive team for the RECOVER initiative. Recover COVID is a multi-part series designed to explore the RECOVER initiative and its research efforts on the symptoms, experiences, scientific understanding, prevention and treatment of long COVID. Today we'll be talking about the recovery initiative overall, including how it's structured and the research questions it aims to answer. We'll also have time to take your questions about the initiative. And it's my great pleasure to be joined today by Dr. Stewart Katz, who's one of the principal investigators at the NYU clinical science core within the RECOVER initiative. This is the portion of the initiative that is leading the clinical research efforts. Dr. Katz, good morning.

### **Dr. Stuart D. Katz**

Time: 03:06 – 03:28

Yeah. Good morning. Thank you, Josh. By way of introduction, I am a cardiologist and a professor of medicine at the NYU Grossman school of medicine. It's great to be speaking with you today about long COVID and recover initiative. I'm looking forward to sharing some of my insights about the initiative and the research effort that's already getting underway.

### **Dr. Josh Fessel**

Time: 03:29– 04:39

Wonderful. Thank you. Now, before we get started, I want to let everyone know about a few housekeeping details. We will be sharing resources and links on Facebook and Twitter throughout today's discussion. We will plan to address questions mostly towards the end of our time today, as some of the questions that may come up earlier on may well get answered as we go. We also want to do our best to catch as many questions as we can, which may mean grouping some questions together that are centered around similar ideas or themes. So if you don't hear your question phrased exactly as you, you have posed it, still be listening for the answer. We may not be able to answer all of your questions, but we're going to do the best that we can.

And finally, I want to be very clear that the information given or discussed today is not medical advice. We're sharing an overview of the RECOVER initiative, as well as resources related to long COVID. If you need medical advice, please speak to your doctor and the healthcare team that knows you best. Okay, with that out of the way let's dive right in. And Dr. Katz, I want to pose the first question to you to start the conversation, which may be one of the more difficult ones that we talk about today, but can you tell us what long COVID is?

### **Dr. Stuart D. Katz**

Time: 04:40 – 05:58

Yeah, Josh. That's a great place to start. And, it is a complex question. I think the background is that we know that some people who have had SARS-CoV-2 infection. SARS-CoV-2 is the virus that causes COVID 19, don't fully recover after that acute infection, or some people may have

new symptoms that may start at some time later after recovery from the acute infection. And these types of persistent symptoms are referred to as long COVID. We know from reports that the most common symptoms all include fatigue, particularly fatigue after doing even mild types of exertion. There's also body aches, headaches, brain fog, or inability to concentrate, normally shortness of breath, palpitations, chronic cough and sleep problems. And that's just naming a few of the more common reports that we receive. We know there are also many other symptoms that people are experiencing. And we also know that overall, this is common. We estimate that 30% or more of the people who are infected with SARS-CoV-2 will experience at least some of the symptoms of long COVID.

**Dr. Josh Fessel**

Time: 05:59 – 06:21

Great. Thank you. And so it sounds like this is a really complex and multifaceted thing or set of things, but very real and persistent and something we have to deal with. And so in light of that, the next thing I'd like to ask you is how is the RECOVER initiative working to understand and prevent and treat this complex thing called long COVID?

**Dr. Stuart D. Katz**

Time: 06:22 – 07:31

Yeah. So to address this very complicated issue in a novel virus, the NIH launched the RECOVER initiative. RECOVER is an acronym. It stands for researching COVID to enhance recovery. That was announced in February of this year, with the intent to bring to their patients, clinicians, and researchers together to study how to prevent and treat the symptoms of these long term effects of COVID-19, this long syndrome. In the spring of 2021, NYU was selected as the clinical science core. And we brought together more than a hundred researchers from across the country to create a recover consortium in collaboration with the matures, patients, caregivers, and representatives of patient organizations to develop the main protocols that will guide the new research to better understand this long COVID. The main protocols were finished in July. And the first phase of adult enrollment started in October. The next phase enrollment will begin in December

**Dr. Josh Fessel**

Time: 07:32 – 07:52

Outstanding. So we're right on the cusp of that. So, hopefully this is a good time to orient everybody to RECOVER initiative. Thank you. And so with all of this activity that's gone into standing this up. What are some of the questions that the RECOVER consortium researchers are going to be working to answer in these studies?

**Dr. Stuart D. Katz**

Time: 07:53 – 09:13

Yeah, Josh. So, what we're trying to in the design of the studies and design of these main protocols is to address the most basic and most important questions about long COVID. And these really are just basic questions because we know this, we really don't know much about how long COVID is being associated with the virus. So first we're saying, how is long COVID best diagnosed?

As we pointed out, we know people have symptoms, but we don't know which are the most important symptoms, which are the ones that are most reliable to actually diagnose and say, "You have long COVID." That's really important because that helps us answer all the other questions such as how many people are getting long COVID. How common is it after a SARS-

CoV-2 infection? Why are some people, but not others getting long COVID? We know it's not everybody, it's a substantial proportion, but not everyone. And so what are the sort of protection factors and risk factors that are linked to the COVID symptoms and how long does long COVID last for the people that do have persistent symptoms? What is their natural history? And finally, and really the most important thing that we're trying to do is to figure out what can be done to help people who are suffering with these long COVID symptoms.

**Dr. Josh Fessel**

Time: 09:14 – 10:01

Excellent. Thank you. Yeah, it sounds like these are some of the very fundamental questions that really need to be answered and it sparks an idea for me or thought for me as you are thinking about addressing these very fundamental questions, I know that you're aware and we've heard people talk about, there are a lot of similarities, at least in some aspects between long COVID and some other autoimmune conditions, post-viral conditions. And there are a lot of different examples of post-hospitalization conditions. And so how might the long COVID research inform these other conditions, these other are issues that people deal with that have some similarity to what we have observed with long COVID?

**Dr. Stuart D. Katz**

Time: 10:02 – 10:52

Yeah, so we do recognize the similarities, at least of some of the long COVID symptoms with these other diseases and including MECFS and POTS, forms of dysautonomia and potentially also some autoimmune diseases. So, we have designed the RECOVER main protocols to include measurements of autonomic function, to better understand how long COVID relates to these other diseases. The RECOVER initiative also includes experts in these diseases within our investigators. And we also will be collaborating with experts in the broader scientific community outside of RECOVER. And our hope is that the research that we're doing within the RECOVER initiative will shed light, not just on the long COVID, but also shed light on these other diseases.

**Dr. Josh Fessel**

Time: 10:53 – 11:17

Excellent. Thank you. Sounds like you've got lots of ears open for all of these issues. And so, in thinking about these studies, who's going to be in these studies that are happening in the RECOVER initiative? Do these studies include patients, for example, experiencing long COVID symptoms right now, or who are the people that are going to help answer these questions?

**Dr. Stuart D. Katz**

Time: 11:18 – 12:26

Yeah, Josh. So it's a big study. The RECOVER initiative will involve tens of thousands of participants, including adult, pregnant, and pediatric populations. RECOVER initiative is also set up to include diverse participants to reflect the nation's populations so that the results can be broadly applied. The RECOVER initiative will enroll patients during the acute phase of SARS-CoV-2 infection. So those are people who are just having the acute symptoms, and we don't know yet what's going to happen after in their recovery, but we're also going to enroll patients that we call post acute. These are patients that have had recover infection in the past with, or without ongoing persistent symptoms. And this includes patients with COVID 19, going back to the start of the pandemic. So we're going to have representation from all the ranges, all the different to times from the start of the pandemic. RECOVER will also enroll participants without

a history of SARS-CoV-2 infection as comparison group to help us better understand and diagnose long COVID.

**Dr. Josh Fessel**

Time: 12:27 – 13:06

Excellent. So it sounds like a really wide net as being cast here to allow these different distinctions to be made amongst the various presentations of long COVID. Sounds like a very thoughtful design. And so I'm hoping that some folks that are tuned in right now may have their interest sparked by this. And as you say, long COVID is an extremely common sort of thing, or seems to be very common amongst those who have been infected with SARS-CoV-2. How can people who are interested in participating in these studies get involved and learn more?

**Dr. Stuart D. Katz**

Time: 13:07 – 13:40

Yeah. So another great question. And we are hopeful that people will want to get involved in this RECOVER initiative. We need participants to step up for us to figure this out. So those who are interested in participating can sign up now. They can sign up on the [recover.covid.org](https://recover.covid.org). That's [recover.covid.org](https://recover.covid.org). One word.org, to be informed when studies are open for enrollment in the area where they live. There are plans to open enrolling sites in all 50 states.

**Dr. Josh Fessel**

Time: 13:41 – 14:53

Outstanding. Thank you. Well, this has been a great sort of quick introduction to a tremendous amount of work on the part of you and the clinical science core and literally dozens of other scientists and clinic and stakeholders and patient advocates and patients and everyone across the board. Let's take a look and see if we've had any questions from the audience.

And we've got a question coming in that says, if I'm reading this question correctly, "Could the efforts that are going on with COVID 19 and long COVID, for example, as part of the RECOVER initiative, do you think there's an opportunity that what we learn in RECOVER, particularly with regard to treatments might inform the treatment of some of these related conditions that we talked about." This person asking the question mentions dysautonomia specifically, but do you think there's an opportunity to learn more about conditions related to but maybe distinct from long COVID?

**Dr. Stuart D. Katz**

Time: 14:54 – 16:17

Yeah, so what I'll say is that we're hopeful that will be the case. And I think it depends on the results of the studies and how, what similarities we identify in terms of the underlying causes of symptoms and long COVID versus some of these other diseases. It's important to point out that the autonomic nervous system is very complex. The symptoms related to dysautonomia are very complex and there are, it's possible that there could be overlapped in symptoms, but having distinct underlying mechanisms causing those symptoms. And so we need to sort through this and that's why we're including these measures of autonomic function in the recovery initiative to try and get at, another important point is that there are right now limited therapeutic options for people with some forms of dysautonomia. And what we're hopeful is by getting more information and recover and using all the sources of recover in terms of trying to develop new therapeutic interventions, that there may be new approaches to treatment that would be good for long COVID and also these other dysautonomia diseases.

**Dr. Josh Fessel**

Time: 16:18 – 16:47

Excellent. Thank you. Yeah, that's an important point I think, is that really understanding the details is going to be a key part of knowing where there are cross applications and where there might not be, thank you. A question coming through, somebody saying that they want to be part of the studies have signed up. And I think I know the answer to this question, but saying no one has contacted me just yet. I want to give you a chance to address that.

**Dr. Stuart D. Katz**

Time: 16:48 – 17:57

Okay. Yeah. Sure. So for people that sign up through the website, we are keeping your information and we have issued some communications to people on the list. Now it's possible that you may have joined after that last communication, but right now we're in the process of developing a system to directly connect the people who sign up with the site that's closest to them based on the zip codes. So that is a little bit complicated to map all the zip codes, all the sites, but we're working on that now, we think we're going to have it together in a couple of weeks and the website should change also so that people should be able to interact directly with the map to figure out where sites are close, based on where they live. They should be able to enter a zip code and see where the sites are. But in the meanwhile, we get this mapping finish and we also identify all the contacts of all the sites so that we can actually put you in contact with someone. We will send a follow up email with that information to you.

**Dr. Josh Fessel**

Time: 17:58 – 18:57

Excellent. Thank you. And that's an improvement, that also gets back I think a little bit to your earlier point about things starting in phases and the next phase, just getting ready to start. And so you also make a really important point to check back to the website frequently, because there are updates posted there with regularity and this is an ever changing situation, just like everything else about the pandemic. So definitely people should check back in, thank you. Have a question coming through that says, and a few people have asked this, "What's being done to try to help educate the larger healthcare worker community, primary care physicians, other specialist physicians about long COVID and about the activities that are going on with RECOVER in specific and with long COVID in general?"

**Dr. Stuart D. Katz**

Time: 18:58 – 20:33

Right, so another very important question. So as you may know, there are many clinics opening up at hospitals across the country that are focusing on these long COVID symptoms, and some of them are being run by cardiologists some by pulmonologists, some of them by neurologists, we have several of them operating at my institution, NYU Langone Health. And what we are doing, is we are starting an outreach to develop essentially a clinical consortium that will operate in parallel to the research consortium, where we will be able to interact with these clinicians, get their feedback on what they're seeing, how and what they're hearing from their patients.

And that's another very, very important stream of information that will help us reshape and guide the RECOVER initiative over time. And an important point about the RECOVER initiative is that we set the main protocols in motion, but the main protocols themselves are meant to be revised over time, we have specific criteria for how we will revise those over time. So we have our ears open to our patients, our caregiver representatives, advocacy groups, and clinicians, so that we

can make sure that we are [inaudible 00:20:27] the RECOVER assessments to have the greatest impact on public health.

**Dr. Josh Fessel**

Time: 20:34 – 21:09

Excellent, thank you. That's very helpful to know, and that sounds like great outreach. I think we're going to have time for one more question, this one is an interesting one, this is a little bit more specific. This is a question coming in from someone who is both a cardiologist by training like yourself, and a long COVID survivor. This person is wondering about hypercoagulability or the increased tendency to clot that is seen in some people after acute COVID and how RECOVER is thinking about that and planning to understand that better.

**Dr. Stuart D. Katz**

Time: 21:10 – 22:31

Yeah. Another really important question. And I'll say that I'm a cardiologist and also a long COVID survivor, and of course, very concerned about some of the observations related to pro thrombotic state. So another very important component of the RECOVER initiative is the bio repository. So we are working with the Mayo clinic as bio repository core for good cover initiative. And we'll have samples of all blood products, including platelets that can be used for future studies. We also have what we're calling pathobiology taskforce committees being formed within COVID. And this will include expertise from within our research, our own researchers from the NIH, and then again, once again, outreach to the broader scientific community through scientific symposia and white papers, where we'll be able to plan mature studies to address this important question about thrombosis but also many other important questions related to the immunobiology of long COVID.

**Dr. Josh Fessel**

Time: 22:32 – 22:48

Superb, sounds like lots of answers to be found there. And actually, I want to take one final question. This one is too important to pass over. Will participants need to have had a positive PCR to enroll in RECOVER?

**Dr. Stuart D. Katz**

Time: 22:49 – 23:45

Yeah, yeah. So the answer is no. We created the entry criteria based on the World Health Organization criteria, which includes suspected probable and confirmed cases of COVID. And the reason we did that based upon a really important fact that we got from our patient and caregiver representatives, and we don't require a positive PCR test for entry into the study. We recognize that such testing was not available at the beginning of the pandemic. And we also recognized that not all people have equal access to these tests. So we wanted to have a representative of the population that goes back to the beginning of the pandemic, a diverse population that represents the nation's diversity, and that's why we designed the entry criteria without that requirements.

**Dr. Josh Fessel**

Time: 23:46 – 24:01

Super important point, thank you. And also for me raises the issue that what I'm hearing you say there is that patients and caregivers have had a key role to play in the shaping of RECOVER thus far. Is that a fair statement?



**Dr. Stuart D. Katz**

Time: 24:02 – 25:01

Yeah, yeah. Absolutely, absolutely. From the very beginning of the development, the main protocols, we had patient representatives, patient caregiver representatives, interactions with patient advocacy groups, and they've all provided important information that helped us shape the protocols. And there's an ongoing effort to do this, both at the level of convening a national patient engagement council that we're actively working on developing right now, and also community effort. We have a specific community engagement group within the RECOVER initiative that's reaching out to all the sites across all 50 states so that we can get input from local patient groups to again, feeding back so that we can adapt the protocol accordingly.

**Dr. Josh Fessel**

Time: 25:02 – 26:07

Outstanding. Thank you. We are approaching the end of our time and it sounds like somebody else may want some more of your time here in just a few moments, Dr. Katz. Thank you so much. Can't tell you how appreciative we are of your time and for all the work that you and everyone has done to stand up the RECOVER initiative, and to tell us a little bit more about it today. I really appreciate also everyone who's joined in to hear Dr. Katz's remarks and to learn more about RECOVER. This was the first event in our RECOVER live series, and so please I encourage everybody come back, stay tuned for more of our live discussions in the coming months. And I'll reiterate what Dr. Katz said earlier for more information and resources from the RECOVER initiative, check out the website, [RECOVERcovid.org](https://RECOVERcovid.org). That's RECOVER, COVID all one word.org. And please also continue the conversation online using the RECOVER live hashtag, that's hashtag RECOVER live. Thank you all again so very much, and I hope we get to see you next time.