Responses to Participants' Questions

The overarching goal of the R3 Seminars is to catalyze a shared understanding of the research being conducted by the scientific stakeholder community within the RECOVER Consortium. The R3 Seminars and the Q&As typically feature highly scientific material intended for researchers and clinicians. For other audiences interested in these topics, a link to the National Library of Medicine's MedlinePlus medical dictionary is provided at the end of the Q&As as a resource to help in understanding the scientific terminology.

This document provides responses* to questions raised by seminar participants related to the following presentations at the R3 Seminar ***Ethical considerations for enrolling invested parties in large-scale clinical studies: Insights from the RECOVER initiative*** held on January 28, 2025 (videos for this and previous seminars are available from https://recovercovid.org/r3-seminar-series):

- ***Ethical considerations for enrolling invested parties in large-scale clinical studies: Insights from the RECOVER Initiative***
  Kellie Owens, PhD
- ***Representative Panel***
  Leah Castro, MA
  Rebecca Letts
- **Moderator: Christine Bevc, PhD, MA**

* Responses may have been edited for clarity.

All Presenters: Questions and Responses

Q. How has RECOVER as an initiative handled invested parties?

Responses:

Dr. Owens: In the end, we know that a lot of study staff and Representatives are also enrolled in RECOVER as participants. It was left up to the individual sites to determine with their own institutional review boards how that process should look. I will say that it's been about a year now since I have been formally involved with RECOVER. So I may not have the latest information, but I know certainly that there are invested parties enrolled and we have been, I think, successfully managing any conflicts that arise from their participation.

Ms. Castro: Similarly, I would have to say I agree. I believe that patients and other non-academic representatives should be included in research like RECOVER because their lived experience is vital to science and helping to understand real world challenges with this lived experience. People give real world input that they live with, which

may have been left out of previous research. That being said, I believe that it is ethical because Representatives do not design, develop, or conduct the studies. They're merely participants.

Q. As a patient and caregiver Representative, why was it important to you to be enrolled in the RECOVER study?

Response:

Ms. Letts: It was really important for me to join because of my experiences, and I didn't want others who knew Long COVID patients and future Long COVID patients to experience what my son and I experienced as early pandemic chronic illness patients with Long COVID and associated conditions. That was something that was traumatic and basically impossible to deal with. And I had many privileges, including family and financial support. I can't imagine what so many people had to deal with. So, I felt like even though it was so hard to speak up, I did. Joining RECOVER as a participant was something I could do for the whole community. And as a Representative, there're many things I can do to help those two things. I can go to the sites and bring back information to help, for example, in the task force plan, to better our study protocols. There were multiple situations where, for example, my first time going to a site visit, I was a bit disappointed because I do have postural orthostatic tachycardia syndrome (POTS), and they did a very abbreviated standing test where I only rested for 5 minutes and didn't stand for very long. And so my heart rate didn't have a chance to rest. I could see that if I didn't know I had POTS and a number of other patients came in, that wouldn't have been caught and they wouldn't get the correct information they were looking for.

So I brought that to my task force—we were actually planning autonomic testing for tier two and tier three later, but that was immediately escalated. And by the time I went to my second site visit, the resting was the appropriate amount of time and the standing was longer as well. And there were a number of times like that and in other things I could do to help the process.

Q. Are there other examples that you've encountered of how the Representatives have been engaged in the process and have been able to improve the studies that are taking place?

Response:

Ms. Castro: Oh, absolutely. I think just the fact that the Representatives are included in the manuscript process to be able to input that experience that you don't get from crunching numbers, you don't get from looking at data—you actually get from living through it, and that's invaluable. The input Representatives are contributing, you can't read about anywhere. You have to live through it to be able to add it. And I think the mere fact that we have this system in place where we have Representatives involved on all of the committees, subcommittees, and more importantly, manuscripts—I think that in itself shows how much of a difference Representatives make.

Q. How many Representatives are involved?

Response:

Ms. Castro: Because we've added some more Representatives to our pool, right now we are at about 115 Representatives across the entire study. We've recently added about 40 new Representatives. And we're making moves, we are adding, and we are contributing and we're doing what we're supposed to do in our roles.

Q. What is the benefit of being both a study participant and a member of the consortium?

Responses:

Ms. Letts: I would like to say there's so many Representatives from all over the country and really so many backgrounds, it's beautiful. Working with people with Long COVID and all of the associated conditions I think is helpful to the RECOVER staff and principal investigators (PIs). Day-to-day, we all deal with quite amazing situations. I was half blacked out and I was talking and this is the kind of way I work, and so it's an experience. And I openly share what my son has dealt with, what I have dealt with, all of our conditions and when we do the RECOVER test as a participant, all of the information that we have and all of the education that patients like myself have had to put ourselves through in order to get where we are is shared back and forth with the research and Long COVID clinical community as well. And that's why it feels really valuable in multiple ways. Even if there are some difficulties and it can be a slower process than we'd want, I think it's something that's valuable for the future.
Ms. Castro: I think that each Representative brings something different to the table, but together we work stronger. So we all work in the same groups, we support each other to again, piggyback off of what Ms. Letts just said, we have shared spaces where we just are able to just feel and express, and it's just something special that's going on amongst the RECOVER Representatives. There's something very special going on. And we get to work with wonderful investigators like Dr. Owens to contribute to amazing science and manuscripts.

Q. Can you speak a little more about the role of Representatives in authorship and in the publication process and what that's looked like in RECOVER or outside of RECOVER?

Responses:

Ms. Castro: What role do Representatives play? Well, we are included on everything. We start with the publication process. We start once we're matched and it's a small subcommittee, the Publication Subcommittee, that does the matching of all the representatives onto the manuscripts. We match all the Representatives to manuscripts. They fill out a survey with interest of the different manuscripts coming down the pipeline. We then match them appropriately and according to how many manuscripts they're already worked on or if they're brand new. Right now, because of where RECOVER is, all representatives that are joining are required to publish and participate in

this manuscript process. Which brings me much joy because I love to see diverse voices on these manuscripts. So once they are matched, there's a kickoff meeting with the lead authors where we go through the rundown of what will take place. So we get a more in-depth idea of what the paper will entail, what the cadence of meetings will be like, how we will be able to participate as far as what roles we will play.

Then, once the paper is drafted, after the analysis of data has taken place, we are also invited to those meetings. We start to circulate drafts of the manuscript where we kind of jump in on different parts of the manuscripts where we feel we can contribute best. Sometimes it's something that we personally experience or have loved ones that personally experience, and sometimes it's something that the lead author may see and will ask us, "Do you mind contributing to this paragraph?" But either way, it is an amazing experience. And then we just wait for it to go through the institutional review board process and get published. And then we are a part of science and history and it's been quite rewarding.

I work in other organizations outside of RECOVER. I work here in Georgia with the American Heart Association as a stakeholder. I also work with Emory on another COVID study. I also work with Mount Sinai, New York and New York Presbyterian, New York on different types of studies. And I also work with Insight as a stakeholder and with the Institute for Health Equity Research at Mount Sinai as a stakeholder and valued member. And they all treat me as an equal partner. And again, it's an invaluable opportunity that I'm very grateful to be available to participate in.

Ms. Letts: I've seen every level and participated at multiple levels, all at a byline level. I've definitely written parts of papers—not big parts, but I've written parts. But generally, we can participate in the design, we can write, we can do what we can do. In some cases, we try to make sure we don't do too much—because, at least for me, it can take a long time to actually do anything with Long COVID and it can take a long time to think.

To contribute our knowledge and our experiences, I've had to, even right before a paper was published, I contributed maybe the very last word. And I've helped at the beginning when we were just trying to figure out where a paper was going. So I think that Representatives are vital, and I hope more research institutions take on patient, caregiver, and community Representatives. I think they would definitely benefit. The funny thing is when you start doing a lot of this, the general research community thinks you are a researcher. So I actually have reviewed papers outside of RECOVER.

I don't come from a medical science background, so most of what I've written is not in this area. It's completely different and not recent. But I have done a lot of advocacy work and helped with a lot of different organizations. I definitely help with a number of different advocacy organizations and do what I can because that is very limited.

Q. What is this co-authorship process like from a researcher perspective?

Response:

Dr. Owens: Wholeheartedly, I'm tremendously grateful for the Representatives we had that worked with us on this paper. At all levels, I think RECOVER is doing this incredibly well in comparison to a lot of other studies I've been involved with. I'll back up and say that, in empirical bioethics in particular, we cannot write guidelines for what we

think the right thing to do is without talking to the people who are actually affected by the conditions under study in whatever we're considering. So it's perhaps even more critical for us than it potentially is for folks who do research in other areas—to be immediately connected to Leah and Rebecca and other people for this paper where we could ask them what things they're seeing as they are living and doing the work that we're talking about here. We cannot write the paper without the perspectives of our Representative authors on this paper.

So we had some ideas before we started. Again, going through these classic research ethics frameworks that can apply pretty universally across a lot of research, but how to apply it and what to consider for a particular project will always have to be pretty substantially informed by the people who know what they're talking about in a much deeper way than we do, frankly. Ethics researchers have experience and tools in asking the right questions, but we cannot know the answers until we ask the people most affected. So it has been incredibly valuable to get their perspectives and to have them challenge us when things are or aren't appropriate. And it's certainly something that I will take with me into other studies, to try to build this resource, and include the budget for it, too. I mean, it's not inexpensive to build this infrastructure, but I think it's so valuable that it will be certainly something that I bring forward.

Q. How do people get more involved in RECOVER other than just being on a trial? How can others become involved in studies like RECOVER?

Responses:

Ms. Castro: I got involved with RECOVER from the work that I was doing in New York with Presbyterian and Sinai. One of the investigators and PIs who was working very closely with RECOVER recommended me and referred me to the engagement team that was part of RECOVER. And that's how I became involved with RECOVER, from the previous work that I was doing in the community and as a caregiver. But I would say word of mouth, so reach out. The information on studies like RECOVER is on the website, as you plugged earlier. The information for the engagement team that oversees everything is where you can reach out and just make your symptoms and your situation aware to them, so that when recruitment begins again in the future, you are right on the top of the list to be considered to join the Representative pool. We are here waiting for that time to happen because it's a special place to be. But I would say to just reach out to the engagement teams.

Ms. Letts: As a patient, there are multiple ways. I guess the most common way would be through social media. And I know that there's a lot of controversy there, but not so much if you have chronic illness. Because if you have chronic illness, social media is your outdoors. It's where you socialize and see your friends, and a lot of the places are actually closed groups. In those closed groups you share studies or humor, ups and downs. And there is definitely information about studies to join and information about conferences, and they're virtual. Especially after the beginning of the pandemic, a lot of them were actually quite affordable. Occasionally a doctor might share a

good study, but it's not that often. And then there are ads. And then you can look them up on specific sites. What are some good ones? I don't know, there's a couple that just list studies, like government ones.

Ms. Castro: I would also just suggest to maybe just ask your primary care provider (PCP). If you know that what you're experiencing is off, no matter if you feel like you're being gaslit, advocate for yourself and just ask your PCP if there are any studies you can get involved in. Advocate for yourself.

Webinar Slides

To request a copy of the R3 Seminar slides, please email RECOVER_ACC@rti.org.

To Learn More

- Information about RECOVER research and to volunteer for studies: https://recovercovid.org/research
- Frequently Asked Questions about RECOVER and PASC: https://recovercovid.org/faqs
- CDC information: Information for the general public and for healthcare providers about Post-COVID Conditions: https://www.cdc.gov/covid/long-term-effects/
- For medical/scientific terminology: https://medlineplus.gov/healthtopics.html