Precision Medicine, *All of Us* and Inclusion, A Discussion for Journalists November 16, 2021

TRANSCRIPT

Welcome to Precision Medicine, *All of Us* and Inclusion. This is the third in a series of four online discussions for journalists this fall, produced by the Hastings Center in partnership with the Center for ELSI Resources and Analysis, CERA, a federally funded project that builds the community of researchers focused on the ethical, legal and social implications of genetics and genomics. We are pleased to be joined by members including Nidhi Subbaraman, a senior reporter for the Journal of Nature; Sandra Soo-Jin Lee, chief of the Division of Ethics in the Department of Medical Humanities and Ethics at Columbia University, and CO-PI of the Center for ELSI Resources and Analysis; Katherine Blizinsky, policy director for the National Institute of Health, All of Us research program. And Carolyn Neuhaus, a research scholar at the Hastings Center. We hope for strong participation from the audience. Please type questions in the Q&A box at the bottom of your screen. You can also use the chat function to share relevant resources. This event is being recorded and will be available on the Hastings Center's website later today. It will also be available on the CERA's website ELSIhub.org. Now I would like to introduce Susan Gilbert, communications director of the Hastings Center, who will say more about the annual journalism discussion series.

Speaker 2

Thank you, hello, everybody, and welcome. The Hastings Center is a bioethics research institute that produces scholarly analysis and policy recommendations on a wide range of ethical questions in health, health care and the life sciences. With our research, we have an equal commitment to public engagement. This year, the Hastings Center launched an annual event series that we're calling Bioethics for Journalists. It is a set of discussions to help journalists identify ethics questions and pursue investigation of those questions on emerging topics in health and science. The series is part of the Hastings Center's Callahan Public Programs, named for our co-founder, Daniel Callahan. It is an initiative established and supported by The Andrew and Julie Klingenstein Family Foundation and the John and Patricia Klingenstein Fund. In honor of Dan, I'd like to express deep appreciation to the Klingenstein family for their vision and support. The theme for this year's series is genomics and society, new developments, new questions. We are fortunate to collaborate this year with the Center for ELSI Research and Analysis, a project led at Columbia University by Dr. Sandra Soo-Jin Lee, who is one of our panelists today, and at Stanford University by Dr. Mildred Cho. Many thanks for this partnership. Today's event is on precision medicine research focusing on the National Institutes

of Health, *All of Us* research program, an unprecedented initiative to collect health related data from at least one million people living in the United States and to build a database of information from people of many backgrounds, ages, geographic regions, gender identities, sexual orientations and health statuses. This session will address the ethical, legal and social issues of this massive data collection that is essential to the precision medicine research. What kinds of diversity are needed in precision medicine datasets? How can precision medicine research help overcome health inequities? What are the clinical challenges to recruiting and retaining diverse participants? It is my pleasure to introduce the moderator, Nidhi Subbaraman, a senior reporter for Nature, who is interested in the impact of research and science policy on society, particularly on vulnerable communities. Welcome Nidhi.

Speaker 3

Thank you for that, Susan. Welcome everybody to this session. I'm excited to be here and excited to talk about a fascinating area of science and research, together with a really stellar lineup of panelists who watch this area really closely. I am a reporter covering biomedicine at Nature's news team, and we'll just sort of be laying out the landscape for you before we dive in to give you a sense of what makes this interesting to me as a journalist and what may interest you in your area of reporting as you watch the space? So, precision medicine is an idea that treatments can be personalized to an individual, to one's particular biology, to your environment, to your family history and to your genes. In some ways, it's an echo of an old idea in medicine, but one that got particularly turbocharged and came into a new level of focus with, you know, advances in technology as far as genetic sequencing went. So, through the through the 2000s and up to 2010 or so, it gave rise to a new level of interest in finding out how to tailor treatments for a particular person's disease based on their genetics and their genetic code. This was an idea as far as the science developed and reached this new level of sophistication. This was an idea that caught the attention of the White House and President Barack Obama in 2018 in a big way. Then that year came the announcement of one of several pretty big science projects that that administration had announced called the Precision Medicine Initiative in 2015 at the State of the Union, President Barack Obama announced it and a core component of that. A government wide program was the All of Us initiative that was going to be housed at the National Institutes of Health, the top public funder of biomedical research in the world. The idea for the program was that it would be a biobank of sorts. It would collect biological samples and patient data and draw up to a million people and study them over the course of 10 years. So really a scale of study into individuals in this program, but also having a dataset that was that big to inform a broader understanding of health overall and the interplay between genetics and the environment and individual circumstances. Kathy Hudson, who was the deputy director for outreach and policy at the time, said to a colleague of mine at Metro, we have never undertaken citizen science at this scale before, so it was really something that was novel in its scope and novel and its infrastructure and novel in its logistics, as well as its promise. So that was 2015. There was an announcement of a funding at the time for the program, which subsequently has grown to up to $1.5 billion over 10 years, authorized by the 20th Century Cures Act in 2016 and in the seven years since the announcement at the State of the Union. Several things have progressed both in the field of precision medicine and the execution of the idea and vision that was the All of Us program, as well as the understanding of what it means to have genetic data and share it in the public at large. So.

Precision Medicine has, I think, shown some promise in a few different ways. I think you may have seen stories about patients with an unknown or incurable disease that they've been grappling with for several years, most of your life and having their having part of their genetic code sequenced and being directed to a particular therapy that instantly remarkably changed their life in sort of in a nanosecond. These were, they were, you know, these stories are really transformative and stunning, but they were case by case by case. They were sort of individual and but they did sort of realize some of the promise of the idea that precision medicine kind of offered. In the meantime, the large scale project that is all about us has also lurched to life. So I think as of 2019 and maybe since then has better numbers for us, a little ahead of that. As of 2019, there were over 200,000 participants that had been enrolled in the program. And as recently, the program had pledged to start returning information to participants who had who had enrolled to share their genetic information or various aspects of their health history. Now, this kind of time point in the evolution of an idea is a very interesting place to be as a journalist and as a watcher. And this is because we're seeing basically a grand vision that was outlined to us some years ago that, you know, with good reason to want to really change the way we think about health and health care come to life with all its messy logistics as well as its potential and its promise. Now it has gone from something that was. An idea for the future to something that you can watch and see in real time what it means to actually participate in such a program, what it means to collect this data and how the various parts of this enormous ambitious operation are interacting together and with the people that it aims to solve. To me, the other thing that makes this point of time interesting is the amount of funding that has been that is that has gone to this program. While All of Us is not the only biobank of its kind, there is a program in the UK, for instance, it is one that has received a significant amount of federal money, taxpayer money and in a sense, is and its goal is to endorse a representative sample of the American population at large. Up to a million volunteers. So all of those big numbers tell me that the stakes are pretty high as this program gets rolling now. It's also matured to a point in time where we could see some of the results of that operation earlier. It was last year, I believe, that the program announced its results of an analysis of blood samples that shed some light on the early months of SARS-CoV-2 transmission in the United States. So we're beginning to see results, scientific results from the program as well. And simultaneously, I think the public at large, your readers, are getting a better sense of what it means to have a genetic identity, what it means to share biological data when big datasets are involved. What it means to be part of that plot. Platforms like 23andMe, and the Ancestry databases, as well as stories like in the news about law enforcement, for instance, mining that kind of data for interests that people may not have anticipated has given readers, I think a more sophisticated and complex understanding of what it means, not just to be, you know, to have electronic data, but to have to have your personal information stored and collected in this way. Of course, this understanding is not at all uniform, and I hope that our panelists can get to that at some point. But I do believe there is a better understanding now and a better responsiveness to stories that examine questions like this when it comes to biological data versus your information, perhaps on Facebook. So, discussions about identity and ethics and inclusion have always been a part of, you know, research that had research that focuses on genetics at large. And this, of course, I mean, this is this has reached a new level of fervor in the aftermath of the pandemic. But it has always been an interesting point of discussion because on the one hand, when you're looking at large databases and

large studies, we know that it is important to include as diverse a sample set as possible for a robust set of results. At the same time, when it comes to genetic data in particular, communities that are perhaps harder to reach but more important to include have developed a level of distrust of the scientific community. That research has been conducted in this space in the past. So I'm very curious to know how this discussion has been evolving at All of Us, as well as what the panelists are thinking as diversity and inclusion in the research place becomes more than ever a focus of almost any aspect of scientific study, and this has become a point of scrutiny. I think in a way from outside observers that has not that I haven't seen before. So, let's see, so that brings us to our list of panelists, we have, Carolyn Neuhaus, a research scholar at the Hastings Center and a principal investigator on two projects on ethical issues related to the All of Us program. We have Katherine Blizinsky, who is a policy director at the NIH All of US program, and we have Sandra Soo-Jin Lee, who is the chair of the Division of Ethics and tenured faculty at the Department of Medical Humanities and Ethics at Columbia University. Just ahead of Dr. Lee taking over from me for her set of remarks, I'll just say a brief few words about her background. Dr. Lee was trained as a medical anthropologist and has experience leading multidisciplinary bioethics research programs on race, ancestry and equity in genomics, precision medicine and artificial intelligence. She is a co-principal investigator of the Center for ELSI Resources and Analysis and is a co-director of the NIH and the ELSI Annual International Congress. She's a fellow at the Hastings Center and has been an economic and social science research fellow at the University of Edinburgh, and has served as the chairperson of the Institutional Review Board at the Cancer Prevention Institute of California, as well as several oversight committees. Dr. Lee was a doctoral recipient of the UC Berkeley UCSF program and medical technology, and has an undergraduate degree in human biology from Stanford University. I welcome her to take over.

Speaker 4

Great. Thank you so much, Nidhi, for that very kind introduction, and thank you, Aashna, for managing my slides, I'm very appreciative of that. Well, I'm delighted to be on this panel and on behalf of CRA and ELSIhub have really delighted that we are able to partner with the Hastings Center on these series of workshops for journalists on ELSI issues that are related to genomics. And today's discussion is one that I'm really looking forward to as it relates very closely to work that I have been conducting alongside Janet Shim and my colleagues, Malia Fullerton, as well as Aliya Saperstein on the ethics of inclusion. And so I'll be drawing on some of that work. In my remarks today, as Nidhi mentioned, when I think about precision medicine as a medical anthropologist, I'm really thinking about it in terms of it being a socio-historical process, if you will, and to think about these initiatives as embedding values, politics, material conditions that really inform the way an initiative will set out the specific trajectory of the questions that the initiative asks, as well as its research practices. Next slide. So what I'd like to do in my brief remarks is to provide a historical context to these particular efforts and to focus on the questions of diversity and goals of inclusion that have been taken up by these initiatives. And so in doing that, I'm hoping that this background will help serve our discussion among the panelists and with all of you in the audience in terms of what it means to ask communities that have not historically participated in biomedical research to volunteer their health data and bio specimens, and specifically asking questions about what responsibilities does this targeted recruitment effort usher in? What new ethical questions do these goals raise in terms of

scientific practice? So how the research was conducted and to what end and what I'll be doing is just sketching out kind of the history and to bring us to the present moment. And I think, you know, we're very fortunate to have Kate Blizinsky here from the All of Us research program who can tell you much more about the current program. OK, and again, I am going to be relying on my colleague Malia Fullerton's some of her work that has really sketched out this history very well. So next slide. So current initiatives such as the All of US program has historical origins that really reach back a couple of decades, shortly after the conclusion of the Human Genome Project in 2004, then director of the National Human Genome Research Institute, Francis Collins published a really prominent commentary in Nature, calling for a nationwide longitudinal prospective cohort investigation that would be designed to draw rigorous and unbiased conclusions about the roles of genetic and environmental factors in health and disease. So this was really a calling for bringing together some of the technologies that had been developed around giant genetics and to marry it with what we understood as environmental factors that have that inform our health and disease. And this effort was one of several that were already underway around the world. This includes, as Nidhi mentioned, the U.K., but also in Iceland and Estonia and Japan, and really many, many efforts on a global scale to come up with these various national cohorts to push forward the study of genomics and environmental factors on health and disease. Now that the success of the study would really depend on the goal of adequately representing the population and here representative, as is perhaps an interesting concept for us to consider of what that means. In the remarks by Francis Collins, I believe that representative was to aim to capture the diversity of the United States and certainly all the different subgroups that consists of the United States. Next slide. So as Nidhi mentioned, there were a number of broader social, political and scientific events that combine to push forward this goal of creating a longitudinal national cohort, including the inauguration of Barack Obama in 2008, when there was a wider discussion of the importance of diversity and inclusion, not just in biomedicine, but in all facets of public life. And then, of course, Francis Collins moved from directing the Genome Institute to leading the entire National Institutes of Health. Subsequently, 2015, President Obama launched what was then the Precision Medicine Initiative, which included several ambitious goals, including the national cohort that Collins had proposed in 2004/5. And that vision, of course, is currently being enacted in the All of Us research program. And so what I'd like to underscore is that precision medicine emerges from a convergence of both scientific and social sociopolitical factors that through the development of increasingly cost efficient genome sequencing technologies and platforms that we all know about in terms of data collection, that integration and the political will to to fund this large cohort is the reason why this initiative move forward in the way that it did. Next slide. So 30 years of public investment in molecular technologies and data integration techniques has fueled promises for precision medicine, and as you, as neatly described, this approach was really envisioned as a data driven method by which we would account for individual variability in environment, lifestyle and genes that would really be tailored to individuals. And of course, to achieve this promise, the promise of precision medicine. This depends on the collection of data, and we see this now in terms of the increasingly seamless data collection and sharing infrastructure that is being built around. For example, each cars or electronic health records that are now linked to bio specimens that contain genetic information, as well as behavioral data that are passively being collected on different patients in different health care systems with partnerships with industry. Next

Slide. So towards the building of this longitudinal national cohort, there is an explicit goal of targeting diversity and what diversity, how diversity is defined has been largely largely defined by minority groups that should be oversampled in order to be able to power differences between between groups and to study health disparities. There is a real effort to capture not only the broad range of genetic backgrounds, but also environmental exposures that might be important in terms of detecting various associations and interactions. And so diversity here means not only in terms of the diversity that we see as defined by social groups and minority groups in the United States, but also in terms of genetic background and the environmental exposures that different individuals might be impacted by. Next Slide. So these goals of diversity really is trying to address a fairly well known problem in genetic research in terms of this genetic diversity deficit. In the same year that Dr Collins moved to head nature investigators and a need and David Goldstein examined population background of samples that were included in what is referred to as genome wide association studies. And what they found was that over 90 percent, 96 percent of such studies really reflected samples from participants of European descent and that even with some updates in terms of that research, the overwhelming representation of genetic samples come from folks who have or claim European descent. And as a result, there is this skew in our databases in terms of who is represented with respect to genetic variation. Next slide. So the failure really for there to be real population diversity, not just in terms of the United States, but really global genetic diversity means that non-European ancestral or individuals of non-European ancestral background would fail to benefit, or the fear is that they would fail to benefit from the fruits of precision medicine research and that there could be the potential for even exacerbating what we know to be health outcomes disparities. It's important to note that this this issue around diversity is one that really is complicated because on the one hand, as I mentioned before, we're thinking about diversity or that genetic diversity deficit is really focused on the sampling biases that have been that have been long known in genetics research. But there's also other axes of representation that may not be taken up as well in terms of the fair representation of other demographic characteristics, such as socioeconomic status or other environmental factors. And so this question of what is diversity and who is actually being enrolled in this type of initiative really comes down to this question of which diversity is being prioritized and for what questions to be answered. Next slide. So before I end, I just wanted to make a couple points regarding the ethics of recruiting populations, specifically those that have not historically participated in research and to raise this question about benefit. We all know that research ethics demands that participants understand the risks and the benefits of research in order to make informed decisions about whether to participate. And I would argue that much emphasis has been placed on identifying the risks historically and less on what constitutes benefit. When we think about research, ethics are a bedrock concept is the focus on altruism. So historically, research participation has been conceived as an act of altruism, meaning that it's a voluntary gesture without expectation of direct benefit. We go to great lengths in our informed consent processes to explicitly disabuse participants of any type of return in terms of their efforts. And altruism is really the hallmark of a paradigm of research participation that insists that investigators make plain that participants will not accrue direct tangible benefits. Next slide. But what we might be seeing now with with the era of precision medicine research is that there's an increasing discussion about benefits and what type of benefits should be returned to participants. And and I'm hoping that in our discussion about that All

of Us program that we can start to think about what this pendulum shift means in terms of a return of value, which I think Kate will probably be talking a bit about. But it raises questions about what constitutes benefit and value, who gets to decide is value and benefit the same for everyone? And does precision medicine research fulfill ethical obligations in terms of benefit in the in the kinds of things that are being returned to participants? And then finally, last slide, I just wanted to raise issues around trust and trustworthiness. Nobody had discussed this in terms of the participation of populations that have not felt comfortable participating in biomedical research. This is a paper that my colleagues and I from the ethics of inclusion published in Science in a couple of years ago. That tries to point out that the history of ethical violations related to protect protocols of inclusion in biomedical research have given certain populations pause in terms of whether to participate, and raises questions about how the research data will be used and how it will be used to help their populations in terms of benefits related to to health. And so I'm just going to leave with the question of, you know, what are the goals of precision medicine research with respect to recruitment of historically underrepresented groups? And how will these translate into equitable distribution of benefits? And I'm really looking forward to the discussion that we'll have with the other panelists. Thanks.

Speaker 1

Thank you, Sandra. I'm a moment here to share my slides so everyone can see my screen. If you can, please let me know in the chat, but I am very, very pleased to be here. My name is Dr. Katherine Blizinsky. She, her are my preferred pronouns, and I'm the policy director at the All of Us research program. The policy office, however, is considerably more than just me. I'm honored to lead a group of truly thoughtful, bright and dedicated people working with me on that policy team, and they're pictured here as well. And together, we help provide the ethical and policy framework in which the program operates. And this puts us in a really unique position to help shape almost all of the aspects of the program. However, the efforts that I'm going to be talking about today are not solely down to the actions of the policy office in the East. They are the products of concerted efforts on the part of a large group of incredibly talented people that have come together to create something that has the potential to be truly extraordinary. So backing up for a moment, I think we've talked a little bit about this in the previous two talks, but precision medicine at its core really acknowledges that each of us is unique. We're unique in our genetic makeup, our social and built environments, our lifestyles, our behaviors and our lived experiences and precision medicine presupposes that the interaction of these factors greatly influenced our health and our clinical outcomes. And the idea of the right treatment for the right person at the right time anticipates a future where we know how these complex interactions happen. And to get to that more knowledgeable future, we need the capability to study the vast diversity of the human experience from a wide variety of angles. And so that's where All of Us comes in. And there are, as mentioned, quite a few cohort programs out there and each serves its own purpose or has a feature that sets it apart from the rest. All of us may not be able to lay claim to being the largest cohort program, at least not for very long. And what makes us different isn't necessarily the data types that we'll be collecting. We may not even have the most comprehensive data for every single line of research inquiry. I think what makes us different is that this is a program with the primary objective of creating a more equitable and inclusive research ecosystem that lays the groundwork for the eradication of health disparities. And this entails a few

things, including engaging and demographically, geographically and medically diverse cohorts of at least one million participants, probably considerably more than that over sampling from historically underrepresented populations. It also entails collecting a rich, multimodal and longitudinal dataset covering elements of clinical, environmental, genetic, behavioral and social data that lend themselves to the relevant areas of research. And it entails making those data as broadly available and accessible as possible while maintaining participant protections to facilitate scientific advancement. I don't think that we're going to reach our goal without an unyielding commitment to meaningful inclusion of underrepresented populations and communities. And I don't think we get there without putting the participant at the center of the research endeavor. We can't see participants as subjects. We must bring them into a partnership. You must have a seat at the table and a voice in decision making. And one way in which the program is attempting to accomplish this partnership is through direct participant representation. Participant ambassadors, of which there are nearly 50 now, are integrated into all levels and aspects of the program's governance structure, serving on central boards and committees, as well as on the Participant Ambassador Advisory Board. In addition, we have twenty five awardee community advisory boards with a total of one hundred and eighty one serving participants that help to steer awardee decisions and operations as well. The program also must meet participants where they are both physically and intellectually. Physically, the program relies on rewards to operate within or serve communities, as well as programs and events to make participation at that local level happen. However, the program also has implemented remote engagement strategies that help bridge geographic gaps, which has been especially important in these times of COVID, and we've also developed some mobile engagement capabilities. So the mobile engagement experience the All of Us journey as it's called or as I fondly like to refer to it, the All of Us bus features interactive stations are designed to help visitors of all ages learn about precision medicine research and the All of US research program. And this bus is something that can travel to events for the head to sites that are less well served by other engagement partners that can maximize direct participant interaction with the program at staff. So right now, at present, the bus tour is on hold. But if you'd like to stay tuned, you can learn more about the bus tour at the website that's listed here. So if we're serious about engaging underrepresented populations, that's going to take more time, so we take more energy and resources than would otherwise be expended and that expenditure needs to be prioritized. But it's important that we also just don't throw money at the issue if we're going to make true progress, if we're going to fulfill our social contract, the society of scientists. This means opening up that black box that science often inhabits and moving towards a more transparent process from the inception through the culmination of the research. It also means acknowledging the mistreatment and abuse certain populations have suffered in the past, both in general and at the hands of scientists, as well as the stigmas and discriminatory practices certain groups and communities suffer to this day that can affect both their health and their participation in research. And importantly, it means a whole lot of listening and learning and that it's really critical and it can't be skipped. The process of enfranchisement and trust building is just that. It is a process and we have committed to that process. But we also shouldn't be embarrassed to ask for help in figuring out how to approach all of this work, which is why All of Us has looked not only to its participants as well as the scientific community and also the experts that are doing really important work in the sphere to the health care provider organizations and federally qualified health centers in

our consortium, who have established trust based relationships with people in the communities they serve, but also to a wide network of community partners who can help us connect with critically underrepresented populations and begin important dialogs. As of October, we have over 50 community engagement and communication partners that help to develop and implement engagement strategies and also build the scientific engagement for specific communities. And they also help raise awareness and generate opportunities for specific community engagement. So this is the lay of the land right now, but we are consistently bringing on new community partners to inform our engagement and inclusion activities. I think we also must acknowledge that we owe energies not only to ensure that we promote diversity within our participant population, but also embrace diversity throughout the program from our staff and consortium members to the researchers. Using the data at our present time has brought a widespread reckoning around social justice and meaningful inclusion, and the program has taken this opportunity to reflect on the choices we've made and take steps to improve our practices. And one area of focus for us right now is our research cohorts. The more we can do to support a diverse cohort of researchers with a wide range of research interests, the more likely the findings resulting from research using All of Us resources will translate to greater equity in the benefits reaped from those findings. We're making concerted efforts to create demographically diverse research, a cohort that promotes responsible and ethical use of data, the returns value to participate in communities, and also that accelerates research impacts. There's definitely some room to grow here is still a work in progress, and we're working with our consortium and community partners to both spread the word about the resources available through All of Us, as well as to solicit feedback from diverse research groups to help the program refine its resources to promote utility. We've also put issued in conjunction with two other NIH institutes, a new nine point one million dollars funding opportunities to support early-stage investigators from diverse backgrounds to bring fresh, creative perspectives and innovative research outcomes. And we're committed to ensuring free access for researchers from a range of institutional and organizational affiliations, as well as community and citizen scientists to establish a truly equitable resource for all. And I think finally here is we need to ensure participant partnerships. We also need to build a program around the participants interests and needs, and this principle has guided All of Us to make some really important decisions about this for the program to make it both more amenable and flexible to people with different expectations and needs. So first off, we believe that almost always the participant is the most equipped, the well-equipped to determine what is best for the participant. So we as a program should maximize participant autonomy and to the greatest extent practicable, empower participants to determine the scale and the scope of their participation. As such, we've structured participation to be a largely modular experience, and our consent process follows this pattern of modularity. So while we do have a comprehensive primary consent that conforms to the requirements of the common rule, we also have a series of other agreements. So there are three additional ones right now. I'm sorry that can set the standard for the wearables. Project isn't depicted here, but there's other agreements allow participants to choose the aspect of the program, which they would like to take part. Moreover, it allows us to deliver information that's relevant to the decision proximal to that decision point to enhance participation for witness. You may notice that we also have four additional agreements that relate to the return of genetic results. That's another decision we made earlier on, which is that both for the sake of

transparency and the ability to offer participants value in participation beyond the philanthropic, which Sandra just mentioned, we would ensure participants had access to their information if they wanted it. So it's been a good deal of time trying to figure out how to return information to participants in a way that is comprehensive and clear with the appropriate support and caveats to protect participant well-being. So more on that in a second. I know that's something that a lot of people are average student. So in addition to our consent strategy, we also provide just in time decision support and educational materials to support participants in making informed choices about different aspects of their research. And even the structure of our data resources has been informed by this focus on participants. So while acknowledging that the privacy of our participants in the security of their data must be paramount, we also need to embrace that the more the data gets used, the greater the potential benefit to our participants and to society. So therefore, the program has adopted a tiered centralized cloud enclave that acts as the sole analytical environment for low level participant data. And that is monitored for researcher behavior. Researchers then are granted additional leeway within this environment. Their admission is authorized. Data users is not contingent upon the approval of a research proposal, but rather on a series of steps that they take as an applicant to gain unauthorized access to the research resources. So in a sense, we're approving the researcher and not the project. Although the researcher that is accomplished by these letters, so means the program does take steps to ensure accountability and oversight, and balances these with researcher education and assistance to help promote awareness and adherence to the principles of the program and to the responsible community research. So I'm happy to talk about those topics and in a deliberate detail during the question and answer period if people are interested. But since we are a little short on time and I know people are interested in some stuff on the return of genomic results, I'd like to focus a moment on, first of all, how we're doing so far. And the truth is, we're on our way. We still have some road left to travel, but out of about four hundred and thirty thousand participants currently enrolled as of about last Saturday night, a little over forty three percent of our participants identify as being a member of an underrepresented racial or ethnic group. There's still an awful lot of white people in our study, but race and ethnicity are again the only axes of diversity to consider when thinking about meaningful inclusion. And taking those other aspects of diversity into account, the majority of both are unknowns and are participants who identify as white are also considered underrepresented in biomedical research in some facet. So overall, nearly 75 percent of All of Us participants identify as belonging to at least one underrepresented groups. This plot doesn't include several other metrics of diversity that we track, including disability status, and if anyone's interested in those additional numbers, please feel free to contact me after the panel. I can dig this out. What progress we've made is definitely a testament to the great work that's been done by our consortium partners and to the NIH staff that support them. I'm not going to pretend, though, that we have found all the answers or even that will adhere to the choices that we've made to date. This flexibility to give in response to change, I think, is important just the numbers show. We may need to adjust our strategies to help promote the participant diversity that we're really endeavoring to reach here. I think it's also one thing to get people in the door, it's another entirely to get them to stay in the program, and the dataset won't be longitudinal if we can't retain the participants who have signed up. So the next frontier for the program is and really must be retention efforts. So how do we convince people to continue to contribute their data and their time and their energy to All of Us?

One thing I promise to come back to that also nicely ties into retention efforts is the return of genetic results. We see the return of results as a way of returning value to participants. Returning value helps participants justify their participation efforts, which we hope over time will enhance retention. Studies overwhelmingly show that participants want their information back and they want to know about themselves, and they see research as a valuable opportunity to learn about their health. The program plans to return a number of types of information, including a variety of genetic engineering results, as a way of providing additional value for participants in return for their participation. Most of those plans are still in the future. However, we began to return genetic ancestry and trait results in late 2020, and of the over one hundred and sixty thousand participants that signed the consent to receive genetic engineering results. Up to this point, a little over ninety five thousand participant samples have been processed, and a little under ninety five thousand participants have been notified about the availability of ancestry and trait results. However, only about sixty three thousand participants, or about sixty eight percent of those whose samples have been processed, have actually gone through the process to receive the results of those people that went through the process, and ninety seven point seven percent, or eight percent, have actually viewed their genetic ancestry results and about eighty nine percent have you four of their genetic trait reports. But of those who have received the results and responded to our brief questionnaire, which is about 70 percent of result, viewers most seem to appreciate what they've gotten back. For the most part, they feel the results are trustworthy and find them informative and satisfactory. However, one of two places where we do see some deviation in those answers is around genetic ancestry. The other is silent version, which is heavily influenced by experience. So it's kind of expected that this one wouldn't be a slam dunk, but that's a genetic ancestry. While participants felt the results were relatively accurate and informative. And while for the most part they were satisfied with the results that they got. Genetic ancestry results left a relatively large number of unanswered participant questions, and to be honest, I'm not shocked. First of all, genetic ancestry is a really complicated concept. It's difficult to distill all of the relevant information into a brief political report, but there's also the fact that we're basing these results on methods and knowledge that was born out of research on overwhelmingly European ancestral populations. And that means the depth and detail of what we can relate to non-European ancestral populations is limited. So while we clearly have work to do on retention, we're still doing a little better than the norm when it comes to racial and ethnic representation. Even in a respondent pool here and acknowledging it, of course, that race and ethnicity are only correlated with ancestry. It's still understandable that in a participant population with a greater proportion of participants with likely non-European ancestry and for whom we can provide less full and detailed genetic ancestry results, there might be a few more unanswered questions and there would otherwise be. I mentioned that this data also suggests the need for growth around retentions, but right now only about twenty six percent of participants who self-identify as belonging to an underrepresented racial or ethnic group signed the consent to receive genetic results, as opposed to about forty six percent of the represented counterparts and only 12 percent of people who identify as underrepresented with respect to educational attainment consented to receive genomic results, compared with 37 percent of educationally represented participants. There are further drop offs again between the consent to receive genetic results and the pursuit and receipt of those results. So these participants may not be actively engaging in the

program again, refocusing the program's attentions on its retention needs. But this may also suggest that participants from certain populations and communities don't value these results to the same degree as historically represented participants might. It also may mean that participants from underrepresented groups have concerns about the safety of receiving those results that aren't being addressed, which also suggests avenues for program improvement around reconsidering value through the lens of cultural humility. So ultimately, while All of Us has been going to do yet and it's a difficult road ahead, we've embarked on a really important journey and one we're committed to seeing to the end and we really hope that the best is yet to come. So I will stop there for now, but please feel free to ask any questions you might have during the panel discussion. It just remains for me to thank our participants without whom there would be no All of Us research program, our consortium partners, my marvelous team without whom there would be no policy office and of course, all of you for listening. Thank you very much.

Speaker 5

Great. Thank you, Kate. And Sandra and Nidhi and to all of you for tuning in and just going to get my slides up. Great. All right, so as a reminder, I'm Carolyn Neuhaus, I'm a research scholar at the Hastings Center and a philosopher by training. So I was really excited when Sandra put up the question about what we owe research participants in precision medicine research, because that's sort of exactly the type of foundational question about the nature and scope of obligations to each other that that motivates my work. In this presentation, I'm going to bring us from talking about the history, rationale and structure of All of Us, which I'm very grateful to, to Dr. Blizinsky for giving us such a comprehensive overview of and really into the future when we do hopefully realize the promise of this ambitious research program for All of Us. And so my take home message will be that when we talk about diversity, inclusion and genomics research, which this panel is about, we also need to be talking about delivering the promises of this research to diverse and inclusive populations. We've seen that the promise of reduction of health disparities being a key part of the rationale for diversifying research participants. But really, I'm talking about the last mile problem once we get them in the door, once we structure these programs, how do we ensure that the benefits and the value that we've been discussing actually trickles down to research participants and populations more generally? So to help locate my research and where I'm situated here, I've made this chart. So at the top, we have literally All of Us. This is really quite US centric presentations of, say, All of Us here in the US. We've just learned about four hundred thousand four hundred thirty thousand Americans are All of Us participants or at least residents of America are All of Us participants. The rest of us are non participants. All of Us participants are recruited at a number of ways, from academic medical centers, from the federally qualified health centers and then direct volunteers. And then among the non participants, there are people who are related to All of Us participants. I'm calling their kin and here I really have in my genetic relations of All of Us participants and then people who really have no ties to the program. And so my research is really situated here thinking about the All of Us participants who are recruited from FQHC's. And then because people don't live in a vacuum and this is genetics research which implicates family members, my research extends to a certain extent to the participants kin who are affected by, in particular the return of genomic research results to All of Us participants. And then when we think about sort of the promises made to the American public and the outset of the Precision Medicine Initiative, we're

really thinking about the rest of us as well. So I just wanted to sort of locate again where my interest in work is, and I became interested enough to FQHCs in particular because they're typically not the sight of a cutting edge biomedical research. They're primary care centers mainly focused on delivering high quality preventive and primary care to anyone who comes in the door, but especially underserved and under and uninsured people in the US. And they're called federally qualified health centers because they qualify to receive special funding from the Health Resources and Services Administration and for special reports and for specific reimbursement types of reimbursement under Medicare and Medicaid. And again, like I said, they are, well, they're nonprofit, tax exempt independent health centers again typically unaffiliated with academic medical centers, where genomics research in particular is typically located in the US. So, you know, I was kind of curious about the decision to include FQHCs as a recruitment site for All of Us and indeed as partners in the All of US research program, in part because the FQHCs again have not been involved in research and as such have not really been involved in conversations about research ethics, about what we might owe specifically to people and research participants who are recruited or participating in research from a community health center as opposed to a hospital or medical center. So this decision, this interest, this curiosity kind of led to coming up with two projects that I'm currently collating with my colleague, Johanna Crane, who's a medical anthropologist from Albany Medical College. And the first one understanding engagement is a qualitative inquiry that's situated at one federally qualified health center that's serving as in All of Us recruitment, enrollment and engagement study. And that study really seeks to understand what motivates individuals to enroll or to not enroll in All of Us, why people do or don't continue participating over time. So is the retention element and how enrollees themselves understand the stated commitment to engaging research participants as partners. So again, how the enrollees understand partnership with the research program. Unfortunately, our data collection has been on pause since March 2020 due to the pandemic, given the in-person nature of our observations and interviews. However, prior to the pandemic, we were able to complete and key informant interviews with 14 of the FQHC staff who are involved in the All of Us activities. And they did share some insights into participants motivations for signing up or declining to participate. So it's a very small sample, but I'll share some of the nuggets from that research that we hope will then be confirmed once we're able to resume our participant interviews. One significant thing that we did learn in those interviews was that staff at the FQHC tha we're partnered with feel quite anxious about the rollout of returning genetic research results to All of Us participants because of barriers that their patients specifically face in accessing recommended follow up care. So if your returned, the result that you're positive that you have a bracket gene or lynch syndrome, something that you didn't know and all of a sudden now find out by virtue of participating in the program, you know what comes next for a patient who's under-insured or doesn't even qualify for health insurance or lives hours and hours from the closest tertiary care facility? These are barriers that prove that their patients face in the normal course of providing routine care that indeed come up on a nearly daily basis, but they're even more formidable with the added wrinkle of being returned a genetic research result both because of the novelty of incorporating genetics into primary care, which is really a long term goal of precision medicine, but also because the research results themselves require confirmatory testing before they can be used to justify the clinical care recommended on its basis. So given what we learned in these key informant interviews, our second project, this is the Barriers for

Caring for Patients Project, convenes five of the six participating FQHCs and All of Us to zoom in on the barriers and identify possible solutions to caring for All of Us participants who are returned actionable genetic information, whether that again, information about a particular disease or syndrome or pharmacogenomics finding that could otherwise direct their clinical care. So I'm just going to briefly mentioned two findings from these projects. The first is that, like Dr. Blizinsky said, a lot of people are indeed motivated to participate in All of Us because they're excited about the return of results. They actually want to be returned the information that could have added health benefits for themselves and for their family. So we hear people saying, I want to do this for my family, for my grandkids. And people are also motivated by the longer term improvements in care catalyzed by the All of Us research program that they hope will then translate into improved care for the people around them, for people in their communities. So we see both sort of short term. I want these results and the longer term altruistic motivations at play, or at least our key informants report that they've seen this. And then the sort of second major finding is that certain gaps in care may make it difficult for All of Us participants from FQHCs or their family members who are implicated in the return of genomic information to obtain the needed or recommended follow up medical service when they receive genetic results. So these include perhaps sort of the obvious gaps in insurance, but also provider gaps and certain social gaps. So for example, one thing we learned is that again, FQHCs sees as primary and preventive care centers routinely refer patients that require specialized care to well, we'll need to refer out, so to speak. But sometimes the closest hospital or specialist isn't sort of willing to take on a charity patient or that people are labeled sort of charity patients owing to their socioeconomic status or insurance status and sort of said, no, we can't take that patient. So people have to travel hours, sometimes across state lines to access affordable care. The sort of difficulty in finding care are compounded by internet literacy, language barriers, access to transportation or internet that all affect a person's ability to act upon recommended medical advice. FQHCs have amazing resources and have developed them over many, many years to help patients who need extra attention to do this. But these so-called patient navigators are already stretched thin can only the work that they've done to coordinate COVID vaccines at a FQHCs bears mentioning here as a shining example of how patient navigator is just absolutely crucial to our public health infrastructure. But, you know, if we are for the All of Us participants who have returned genomic information or their family members who may require this sort of complex navigation to follow up on research results, what do we do for a workforce that's already quite stretched thin? And then thinking longer term as primary care centers become the site of precision care? How can we create a sort of sustainable payment model to make sure that this can happen? So ultimately, you know, these projects at the Hastings Center are our calls for, I think, action and accountability. I too hope that the data generated through the All of Us research program will produce knowledge that reduces health disparities, but without attention to this last mile problem, how to put that knowledge into practice. Given the structural forces, given that the structural forces that have led to massive health inequities and inequalities will remain, the point being that inequitable systems of care provision cannot be undone by genomic research alone. We really need to think more broadly. So who needs to be involved? I think first, the participants, this has been, as is already acknowledged by the All of Us research program. It's acknowledged in our in our research to right to understand what it means to return value and attention to what are the various and particular barriers that they in their

communities face to realizing both the immediate benefits of knowing about their genomic medical to knowing their genomic medical information and longer term, about the promise of precision medicine. But beyond participants, the real the responsibility to return value to research participants and to the American public falls on a number of actors. So not just the participants or their providers, and really not just on researchers or any one research program. So I want to state clearly that this is not solely the responsibility of All of Us. The responsibility is distributed to research funders, health care funders, insurers, policymakers, medical centers, pharmaceutical companies and patent lawyers, and it goes on and on and on. And I think this is somewhat obvious, but it's quite unfortunate that our ethical frameworks for thinking about what's owed to research participants, typically a sort of are premised on a sort of dichotomous relationship. We've got the participant and the researchers and the responsibility to provide ancillary or follow up care is conceived only within the context of this relationship. But I think that model has shown to not be sustainable, and it really places the responsibility to provide population level precision care. So really, you know, and we'll argue in this project, it's that it's the federal government as the primary funder of precision medicine research in this country and the actor with the most power and authority to do so. That has a special responsibility to make good on the promises that it's made to research participants and to the entire American public. So, you know, in terms of what needs to be done, I don't want to spend too much time here so we can come back to in the Q&A. But I do want to tease a forthcoming issue brief coming from these projects that will be sent to all participants in this forum and disseminated quite widely that will outline federal strategies to create sustainable pathways for precision medicine in practice. At the sites that we're talking about at FQHCs, which is another primary and preventive care sites short of passing a single payer or universal health insurance program. So again, I won't spend time there, but it's really addressing this the last mile problem of delivering improved care based on the research findings that we that we do sincerely hope will come from All of Us and other precision medicine research initiatives. And, you know, I think ultimately there's also, you know, accountability efforts that need to be that need to happen here. And I think, you know, and I'm really glad that in a forum about diversity and inclusion of precision medicine research, we can also talk about delivering the value of the benefits, the promise of this research to diverse and inclusive audiences. Because I think that we've tried to sort of segment these two things historically and that has not led to major advances in actually how we deliver health care or changes in how we deliver health care. I think it's quite curious and unfortunate in this country that we routinely see bipartisan support for health research and then that bipartisan support dissipates when it comes to actually funding health care. And you know, there's a place, I think, for researchers, whether it's in the ethics and public health and qualitative research side or people on the genetics and biomedical research side to say yes, we are doing the work that will sort of catalyze and create the knowledge that is needed to reduce health disparities. But we can't do that. We can’t actually deliver on that alone. And we really need to have alliances with journalist advocacy groups and policymakers to actually see those benefits manifest. So I guess I'll just finish by saying, I hope that the conversations like this and the projects that we have can create just a little bit of progress toward actually again delivering the promises. So I'll stop there. Thank you very much and look forward to the discussion.

Speaker 2

Thanks, everybody, for those phenomenal presentations. It was hugely informative, and I'm excited to get a discussion on those rolling. I'll start with just a general question to all of our panelists, which is something I ask of researchers, but I'm sort of encountering any new space in your view. What is one issue that or story that is going undercover that needs more attention from reporters that is worth the public's attention that you're not seeing up there at the moment? So this is for all three of you.

Speaker 3

So that's a very big question. So something that needs more attention. I actually have a question that that I wanted to ask Kate, so maybe that's my way of of answering this question. But you know, we in my brief remarks, I alluded to what we see, I think is a pendulum shift in terms of thinking about benefits and what's owed to participants now no longer thinking that it's just altruism and that nothing is owed to participants. And I'm curious as to how value is being constructed in the All of Us research program. And I'm struck, I guess when I saw that slide of the types of results that are being returned, at least at the in the beginning of the program, things like genetic ancestry test results, you know, whether or not you react to cilantro, you know, that list looks really familiar to me. It looks like what was returned through 23 and me and some of the direct to consumer companies and what some people described as recreational genetics. And I'm just wondering in terms of how the program is thinking about value and return to participants, what do you think about the way in which capital and the and the direct to consumer industry has shaped how we're thinking about genetic results? And in particular, I'm thinking about, you know, moving forward in terms of kind of the rationales that were invoked early on with the Precision Medicine Initiative in terms of addressing health disparities. How do we reconcile this? I mean, you alluded to it because you're finding that there are differences, right, in terms of how people are receiving these results. But I would love some insight as to how we should be thinking about this.

Speaker 1

Wow. So again, I can't pretend that I have all the answers, and certainly this is not something that we define in the policy office. I think that's another place where we inform some of those discussions. But really, a lot of this happens outside of my purview and in communications with our participants communities as well and with our community partners. So I think there is a lot of that definition of value that comes from those communications, from the process of engagement with those groups. And it's also a process that's currently being refined.

Speaker 3

I think the initial phase of returning these more recreational types of genomic results, rather than starting with health related results, was to give us an opportunity. It's on a slightly less well, it's to give us a little bit of a buffer before we started returning health related results to experiment with what return actually looked like. What were the types of questions that people had? What was the support that they needed? How much were people especially interested in getting those reports back and doing that in a slightly safer space with the slightly less contentious type of results? But yes, we do run into a loss that comparison with the direct to consumer genetic testing, and I think that has been a challenge for us to to really figure out how to set those expectations. But we're also thinking about what what do people want to know about themselves? And I think there's that again, that calibrations over time about what that means. But it's also a way for us to continue to educate

people around genomic results and to keep them interested in learning more about the scientific results about themselves. So priming the pumps with the genetic ancestry and trait results in order for us to set up that longer term engagement strategy with different types of results down the road.

Speaker 3

Thanks for that. I'd ask Carolyn Neuhaus if she has anything to add.

Speaker 5

I don't have anything to add on this, but I think to go back to your question, you know, I don't want to sound like a broken record, but it's really about actually creating the infrastructure that would allow programs like All of Us research program to have an impact and return meaningful value, right? It's not enough to just learn one day that you have a predisposition to a particular disease or have a pharmacogenetic result that means you shouldn't be prescribed a certain medication that needs to be integrated into EHRs. You have to have providers who have the training on how to utilize that information properly and clinical care payment and assistance, getting the care that's recommended and what we're hearing from the FQHCs, I don't want to speak for everyone or pretend that our research is not complete, but is that there are real concerns about the ability to translate this knowledge into meaningful benefits and improved health and health care of their patient population. And so that, to me, is sort of the biggest ethical scandal here, and there needs to be a lot more accountability for actually translating. And it's not just a translational problem of translating research into practice, but of actually building the infrastructure that when that translation can happen, it actually again trickles down. So I think that's just a line that kind of needs to be in every discussion about the ethics of inclusion and precision medicine research.

Speaker 3

Can I ask if Dr. Blizinsky has any response to that particular concern because I was also very interested in that axis of diversity that that came up? So how,what do you believe the NIH, All of Us' role should be in, you know, reaching patients who may not have the resources to address the health care issues that are raised by such a program? And how is All of Us currently thinking about that question? Is All of Us thinking about that question?

Speaker 1

Yes, and I think in part, thanks to Dr. Neuhaus, we are really trying to actively make some inroads in those areas and specifically around thinking about when we start to return health related genomic results, how do we do that in such a way that somebody can take those results and actually do something with them? You know, given that these are returning research results, not clinical results, there are some boundaries there. But what if somebody can't go to their provider and have tests run that would verify those results? Like what happens in those situations? And I think one of the things that we are beginning to think about and beginning to set up is, well, what about if we do give certain people who come back with like, for example, certain types of positive results? What if we do run those clinical tests? What if we do facilitate that process of getting them, at least those test results and making that warm handoff to a care provider and equip that care provider to actually utilize those results in the care for the patient? It is a complicated and sort of thorny issue because we're crossing into territory between what it means to do research and what it means to do clinical care. And we don't want to violate that boundary in a way where there's no walking that back. But I do think that Carolyn brings up a really, really important issues that we can't just plop these results

into people's laps and expect that to be good enough. So I would I would encourage. Dr. Neuhaus to be patient with us as we go through this and please feel free to come to the program if you have any great ideas. But stay tuned for that. That definitely is in the works.

Speaker 3

Thank you for that. As a reminder, a question in the Q&A box, if you have them for our panelists, I'll take one from Lee Naruden, who added a question here that touched on something that Lee brought up as far as axes of diversity beyond ethnicity and race. I think this is for again, Dr. Blizinsky. She says your focus on diversity seems to be primarily on race, but on other categories of diversity, for instance, disability, etc. are regulations from the ADA taken into consideration as far as production and participation?

Speaker 1

So the answer is yes, we focused a lot of attention on race and ethnicity in this presentation because it's one of the most frequently requested types of information about the program. We do track, though, a number of different diversity metrics, including disability status, as well as access to health care, income, educational attainment, geography, age, sex assigned at birth, gender identity and sexual orientation. And that's right now. So it's quite a scope, but it's certainly not just race and ethnicity.

Speaker 3

Thank you for that. Let's see another question I had I had seen here that touches on the issue of participation in this kind of research is the question of participant partners I think folks had. An anonymous attendee asked you, the All of Us program views, participation of partners, what is the kind of relationship that is envisioned by that term? And there was a response to this to say, consortium partners rather than participant partners. But I'm actually interested in the answer to both of those things when you talk about partnerships and partners. What does it mean, especially in the question the circumstances of research participants.

Speaker 1

OK, well, then why don't I start with that? So I think, you know, the part about maybe partnering with research participants is really bringing them into the sphere. That's usually just inhabited by scientists. So we're mounting this enormous program and we're mounting it supposedly for these groups of people. Well, we need to bring them into the planning process. We need to bring them into the decisions that are being made about how the program handles their data about how the program interacts with them, about how the program, you know, oversees the use of that data that monitors the use and enforces the principles of the use of the resources. So that's what I mean by participants there is that really is not seeing them as subjects, as these sort of outside entities upon which our focus is directed. But as part of the process of actually building the program and launching the program and implementing it. As we turn to our consortium partners, so we make awards to a variety of different types of organization and one type of organization that we do make these awards to our people who are focused on community engagement in a variety of different ways. And I call them partners because to be very honest, we couldn't get the work done if it was just NIH doing this. It would be impossible. So we work very much hand-in-hand with these organizations in order to get whatever happens in this program done done. So that partnership is just because we depend heavily

on them both for the energies that they put in, but also for their expertise and they are an integral part of our hopeful success.

Speaker 5

One thing I'm interested in in the context of our participant interviews is it's really an understanding exactly this what partnership means to the participants. And one thing that I'll be really interested to find out and Dr. Lee, I speculate you might have some insight in this from interviews you've done at the academic medical centers. But as to when, to what extent participants see their partnership with their health care provider organization where they were recruited from. So with the FAQCs or with the Academic Medical Center, you know, sort of seeing that as, Oh my, you know, they're doing research, they're engaged in this research and partnering with them versus a sense of relationship to the NIH and All of Us research program. So to what extent is the site of recruitment doing a sort of mediating role in facilitating an understanding of partnership is something I think I certainly don't know at this point, but I'm keen to find out.

Speaker 4

Yeah, no, I think you're absolutely right in that the you know, the different academic centers, I think, are chosen in part because they do have some relationships with the communities that are being recruited or targeted for recruitment. You know, it brings up this issue around how we do research in in the U.S. and elsewhere in terms of really thinking about study-to-study and having all of the infrastructure around community engagement being kind of built up with every study. And instead, it may be helpful to think about kind of institutional trustworthiness that supersedes individual studies, but really invests in communities as long-term relationships that go beyond any one project. And I think that's something that we've been thinking about in terms of our ethics of inclusion studies. How do you how do you foster those long-term relationships? What are the kinds of responsibilities on the part of institutions that are not just conducting research, but of course, delivering care? And this is exactly where you know your points, Carolyn, become really important because I think for participants, they see this as not as a kind of bifurcated system, research and clinical care. They see it as a continuum. And so, you know, these issues around trust and trustworthiness really do need to kind of address that. Everything from, you know, do I trust the study to do I trust this institution in terms of the care that I'm getting.

Speaker 3

I see. One last question that launches off this very point. And so this is to anyone who wants to take it. This is Esther Berkowitz who asks, “Is there an opportunity to use some project funding to ensure we fund participants medical needs as identified in the study?” So to Kate Blizinsky, I ask is this possible? and to Dr. Lee and Dr. Neuhaus, is there precedent for that in other research programs and as far as the feasibility and ethics of that? What are we looking at?

Speaker 1

Who wants to go first?

Speaker 5

The easier question is for you, actually, is this the sort of can we afford it?

Speaker 1

I must admit that I hold absolutely zero purse strings. It's one of the great luxuries of being the policy director is that I don't really spend a lot of time thinking about certain aspects of the money part of

this the really practical expenditures of funds that the finance and operations team would be much more equipped to answer. So if you don't mind, please feel free to email me directly and I will hook you up with their team.

Speaker 5

I think from my own standpoint, it's not really a desirable solution, so there's a sustainability question, can studies like if this, is the precedent and it kind of is, and it falls under a framework called like ancillary care benefits. And that's sort of technical ethics term for when we sort of say a research team or a researcher has an obligation to provide, you know, the extra follow up care or some forms of medical care to their study participants by virtue of having entered into a relationship with them and showing them certain things. But really, that sort of like creates a special class of citizens. So it's sort of, you know, only the research participant is then sort of a recipient of this care. So it's certainly not broadly shared. And then the other thing I mean, there's there's a problem in the US, given that the mandate of the NIH is is to produce health research. It's sort of like a square peg round hole problem. It's just it's not their remit from Congress to provide medical care. It's the remit of other agencies. And so I support instead of sort of a multi-pronged solution that acknowledges that the NIH is really good and really well equipped to produce knowledge. And we hope that that knowledge will be really valuable to a lot of people, but that they're sort of not in the business of providing care. And it falls on other agencies and the funders of the research to make sure that those agencies are equipped to provide that. So in the short term, possibly, yes, right? Maybe it's better than nothing. It's certainly better than nothing to potentially provide the confirmatory blood tests to produce a clinical result. But in the longer term, it's not sustainable.

Speaker 3

Thank you so much for that. I'll take a second to thank our panelists for a really rich discussion here and to everybody who participated and tuned in. Thank you so much for joining up. I'm going to turn it back now to Aashna Lal at the Hastings Center to close things up, as we're at a time.

Speaker 1

Great. Thank you so much again, everyone for joining us today. A recording of the discussion will be available shortly on the Hastings Center's website www.thehastingscenter.org and on ELSIHub .org along with resources. We would also like your feedback on the event, so you will receive a brief survey via email shortly after the event. Please return it as soon as possible. We'll use your feedback to improve future events. Please join us on November 30th for the next discussion in the series, “Addressing racism in medical research and publishing” with Vabern Watts, Equity Director of Health Affairs, Fernando de Mayo, Director of Health Equity Research and data use at the American Medical Association, and nd Mildred Cho, associate director of Stanford University's Center for Biomedical Ethics and a PI on the Center for ELSI Resources and Analysis. Thank you again and have a great rest of your day.