ELSI Friday Forum
Biobanking in the Era of COVID
Friday, January 8, 2021

TotalCaption
Captioned stenographically by Joshua Edwards, RDR, CRR

This text is provided in rough draft format. Communication Access Realtime Translation (CART) is provided in order to facilitate communication accessibility and may not be a totally verbatim record of the proceedings.

>> DR. GOLDENBERG: All right. Let's get started. Thank you, all for being on. We would like to start by wishing everyone a very Happy New Year. I'm Aaron Goldenberg from Case Western University in the Department of Bioethics. And we would like to welcome you to our third ELSI Friday Forum and the first for 2021.

These forums are held on the second Friday of every month for one hour from noon Eastern time for an hour. And then we have another Zoom room as many of you know for an informal discussion that will start immediately after the panel for 30 minutes.

The link to that afterforum panel is in an e-mail that was sent to you today for everyone who registered. It will also be in the chat a few times over the session. So you can link to it through that. And we hope to see many of you in that session as well.

As a reminder for those of you joining us for the first time, the ELSI Friday Forum is a new monthly series of

the Center for ELSI Resources and Analysis, otherwise known as CERA. For those of you who may be new to CERA, it's a multi-disciplinary multi-institutional center that provides resources to support research on the ethical, legal and social implications of genetics and genomics, otherwise known as ELSI, and serves to connect a community for scientists, scholars, policymakers, journalists, members of the public, and others to engage ELSI issues.

CERA is funded by the National Human Genome Research Institute at NIH and is managed by teams at Stanford and Columbia Universities in partnerships with the Hastings Center and Harvard University. CERA's online platform, ELSIhub.org -- the link will also be in the chat -- launched a few months ago. And we encourage you to access resources there including the recording and transcript of this forum as well as other forums, associated reference material, as well as an ELSI literature database, research instrument repository, scholar directory, news and events and much more. Please go to the website to sign up for newsletters and other events like this one at ELSIhub.org. Again, that will be in your chat a few times over the session so you can link to that if you would like. You can also get daily updates and news on Twitter @elsihub which will also be in the chat.

Just a few housekeeping before we get started. If you wish to use closed captioning, please turn on the CC

button which will be at the bottom of your screen. We also encourage an active exchange of ideas between our panelists. And all of the panelists' presentations will actually be very brief today, so you will have a significant chance to have some time for discussion.

Please use the Q&A button which you will find also at the bottom of your screen. And you can ask the panelists questions. You can register your enthusiasm for a particular question and elevate it up the list by using an upvote button in the Q&A box. So if you like the question or you want to second a question, you can go ahead and add that. The chat box is also available for further engagement where you can find links to resources referenced in today's discussion, articles and such. If you have any questions, please e-mail info@elsihub.org at any time for any questions.

Now let's turn to today's topic, Biobanking in the Era the COVID, and more generally the implications of biobanking in the context of pandemic and other public health emergencies. Over the course of the last year, biobanking and the used of stored biospecimens and data has become a crucial element of the medical and public health response to COVID-19.

First and foremost, the utility and importance of biobanking is evident in the need to access blood and tissue samples from patients to support a ramp-up of COVID related research including studies to develop interventions and

vaccines.

Second, as hospitals and academic medical centers have had to limited in-person recruitment for traditional research, previously established biobanks can also help to sustain and drive other non-COVID research programs during the pandemic by becoming a vital source for biospecimens and data.

Finally, research on the impact of COVID on biorepositories may reflect the larger challenges of doing science during a pandemic more generally. For example, addressing the research ethics and IRB challenges of biobanking during the pandemic may also mirror similar challenges of addressing human subjects' protections and needs for other kinds of expedited studies.

Additionally, it's vital that we don't lose sight of the important conversations that we have had over the last two ELSI Friday Forum sessions regarding institutional racism and social justice and to question how well understood minority populations -- how well minority populations are represented in biobanks and other studies. This is especially important given that many of the populations that are generally underrepresented in biobanks are bearing a disproportionate burden of the COVID pandemic.

Today's session will explore the ethical and governance challenges of biobanking during the pandemic, including the creation of new COVID biobanks and the

repurposing of existing COVID-19 -- repurposing samples for COVID-19 research.

We are fortunate to have two panelists who spent considerable time thinking about working on these issues and addressing the unique intersection between biobanking stored issue and biospecimen research and the COVID-19 pandemic.

Our panelists today will include Kyle Brothers who is an Associate Professor of Pediatrics and the Endowed Chair for Pediatric Clinical and Translational Research at the University of Louisville, where he directs the Division of Pediatric Clinical and Translational Research and is a member of the Institute for Bioethics, Health Policy, and Law.

Dr. Brothers is a pediatrician and a bioethicist who conducts research on ethical issues in the translation of genomic technologies to clinical practice and research ethics issues encountered in contemporary models of biomedical research.

Second, Sara Hull will be talking with us. Dr. Hull directs the Bioethics Core for the National Human Genome Research Institute at the NIH, which provides bioethics education, consultation, and administrative support to investigators in the Intramural research program. Dr. Hull also serves as a Chair of the NIH Intramural Institutional Review Board and is on the faculty of the NIH Clinical Center's Department of Bioethics where her research and

capacity-building interests focus primarily on the intersections between research ethics and genomic research.

For those of you who can join us in the panel discussion after this main session, we are also fortunate to have a number of colleagues who have been working with Kyle, Sara and myself who will be on hand during that discussion and will be able to join and add to our conversation. These include Benjamin Berkman from the NIH Department of Bioethics, and Jean Cadigan from the Department of Social Medicine at the University of North Carolina at Chapel Hill.

Our speakers' brief presentations will be followed by a moderated audience discussion and Q&A session. I encourage you to write your questions in the Q&A box, and I promise to get to as many as I can. So with that, I am going to turn over the session to Kyle Brothers who will start us off.

>> DR. BROTHERS: Thanks so much, Aaron. And hi to everyone. I was looking at some of the names as folks came on the call and noticed I recognized a lot of names. So I really appreciate you all being here to engage in this conversation with us.

Just from the very beginning, I'm going to be talking more on sort of empirical side of this issue and talking about the impact of COVID-19 on ELSI issues and biobanking. And I just want to recognize that I'm the

presenter here, but this is really the joint work of myself, Jean Cadigan, Aaron Goldenberg, and actually Sara Hull and Ben Berkman, also contributed to this survey. So I just want to make sure everyone knows I'm just the messenger here, but this is a really great team of folks. Next.

Just want to briefly introduce an idea that is going to come up in the course of our conversation, and I just wanted to give some context. We are going to be talking about what Jean, Aaron and I have been calling neglected issues in biobanking and the idea here is that most of conventional bioethics around biobanking coined around the book ends of biobanking which really means the beginning of this process of the recruitment, enrollment and consent. And then at the end of the process where we are talking about sharing data, return of results, those kinds of issues. And really the middle part of this is sort of the operations of the biobank and a lot of those decisions that really have ethical valences, get ignored. Or at least are neglected.

And Aaron actually had a grant one time where there was a comment that this is just about biobank operations. And the review said that. So we really wanted to highlight this as a set of issues where there's a lot of ethical importance, and we don't want to exclude those topics. Next slide.

So the ethics issues between the biobanks, between the bookends, I just want to highlight why we think these are

so important from an ethical perspective, even though they may seem on the surface just like operational decisions.

Really the key issue here is that if the biobank is failing to use the donated samples to benefit society. So if it is not bringing in samples and then having folks utilize them, then it's breaking its promise to donors. The promise was that they would be those samples would be used to benefit society and failure to use them means we are not benefitting society.

Also, you know, when you think about the risks and benefits of biobank participation, if we are collecting samples but not using them, then the donors took on a risk in terms of the privacy and confidentiality primarily. But then the lack of societal benefits means that risk was not balanced by a benefit.

So we really think this is quite important and interestingly in our other work, we have heard a lot of biobankers use this language to talk about the importance of having their samples be utilized. Next slide.

So not to put too fine a point on it, the issue we are talking about are utilization, sustainability and stewardship, all of which probably recognize sort of operational issues and also an ethical valence. Next slide.

So I am going to talk now about our survey, and this is kind of our working time, international survey of

biobanks on the impacts of COVID-19 with the ELSI-related policy and practices. Next slide.

This was an online survey of the ISBER membership. I don't know if all of you are familiar with ISBER. It's the International Society for Biological and Environmental Repositories. It's an international organization, very successful and has a lot of engagement from folks around the world. You know, looking for support on best practices and biobanking from what kinds of tubes to purchase all the way to, you know, consent, all kinds of issues.

And so really they were the perfect partners to do this survey with. And The ISBER Science Policy Committee was really the platform through which we were able to partner and distribute the survey. I have at the end of the slides some recognition of all the folks at ISBER who helped support this work. The survey was actually in the field from November 23rd to December 29th. So I think we made the organizers a little nervous as we were analyzing data up to pretty close to today. Next slide.

The survey includes both qualitative and qualitative elements with a focus on issues that we thought would be important to explore within the domain of ELSI and those include consent and recruitment, sample and data sharing, privacy and security, IRB and regulatory issues, governance, and then community engagement. And I just want to

be really clear, the findings we are presenting here are preliminary.

Obviously we are not going to present anything we don't think the data supports, but we may really as we dig deeper into the data be able to add some nuance to what we are saying today. Next slide.

Okay. The biobank, we actually had 96 responses from around the world. We were pleased with this response. Next slide. And we included some sort of demographics of the biobanks that were responding. Most of them were from academic institutions, but we did have good representation of nonprofit organizations and government institutions as well as a few private companies. Next slide.

And we actually have, we asked the question in terms of a country so we could be really specific. But I simplified that for this slide. Most of the responses were from North America and Canada. I don't think we had any from Mexico. The rest were distributed around the world, Middle East, Oceania, a strong response from Australia, New Zealand as well as Tunisia.

So we were pleased to kind of get some perspectives on these ELSI issues from around the world which is great. Next slide. This is a little bit of a complex slide, but we thought it would be helpful to give some context. We recognized that sort of the framing of all of our questions

really depended on where the biobank was and, you know, in its life course. And so we had a number of questions at the beginning really to sort out who are we talking with?

So there were four respondents that said that they were involved in a nonhuman biobank, an animal biobank. There was actually one doing work on COVID collecting samples from pangolins and bats, right, Aaron? The questions were framed for human biobanks, so we didn't have additional questions.

Then we had 87 currently operating and they were operating before the pandemic started and five created specifically in response to the pandemic. So among the biobanks that were operating prior to the pandemic, five were not currently collecting samples. And interestingly none of those five said that they had stopped collecting samples as a result of the pandemic.

There were other factors at play in their not currently collecting new samples. But the majority were currently collecting samples. And we did find one that is collecting only COVID samples, but then the remainder were split pretty evenly between those that were collecting only non-COVID samples and those that were collecting both COVID and non-COVID samples.

And just to give you an idea, you know, a COVID sample was framed as collection a sample specifically for the purpose of studying COVID. So it could be COVID-positive

patients or COVID-negative patients. But really, you know, the collection was focused on COVID versus, you know, everything else that these biobanks do.

So next slide. This is really our primary quantitative slide for you today. We asked the question about each of these issues, and asked the biobanks to rate the degree to which the biobank had impacted their policies and procedures. And as you can see, the largest, the category where the largest proportion of biobanks reported moderately or extreme affected their operations was in consent or recruitment which is may be not that surprising.

This is really a space where the biobanks are interacting with the community which, of course, is where the pandemic creates the most challenges. Community engagement was next, probably reflecting some of the same challenges with interpersonal interaction. And then governments IRB and regulatory issues or sample and data sharing. Privacy and security was low which I think is probably not that surprising because a lot of those issues are really involve computers and not necessarily people. Next.

Okay. So getting into the qualitative data that we have, I just pulled out a few key issues. There's a number of other important issues that I think we will be able to look at in the future. But we have qualitative data on consent and recruitment. And, you know, this is probably intuitive. They

said consent was difficult as interacting with patients posed a risk to the individual doing the consenting and it used up precious PPE.

So obviously this is, you know, a stage of biobanking where there's an interface between individuals and that creates some challenges. And then this is an interesting point we can come back to. This biobank said the IRB approved documentation of verbal consent with the allowance to mail copies of the consent and that did not have to be returned to the biobank.

So unpacking that a little bit, what they are saying is they were allowed to utilize a method of obtaining consent that had not previously been acceptable or approved by the IRB that just involved getting verbal consent and then sending the participant an unsigned copy of the consent with no requirement to get written consent back.

So we are going to talk about this maybe in the discussion, but one of the questions that we had going into this was whether there are practices that we sort of have become typical, typical practices and that are supported by research ethics, that actually in COVID we are willing to change those practices. So the question is, if we were willing to do it during COVID, does that mean they were probably ethically acceptable all along?

Or is there something special about a pandemic that

makes it permissible to do something slightly different than what we would normally consider permissible? Next slide.

The next topic was utilization. And this is interesting. We had the full spectrum on this topic. The first respondent hereby says the pandemic has improved the sustainability of our biobank. There's been a 25 to 35 percent increase in the number of inquiries, that's inquiries for data sharing, that we are receiving. And then there's the opposite end of the spectrum.

Most non COVID-19-related research has been drastically reduced or halted entirely. This has resulted in not as many specify requests for existing specimens. I just want to point out the survey was in the field November and December of 2020. So we are not talking about March of 2020. It seems that these biobanks are still observing drastic effects of the pandemic. Next slide.

So talking about IRB and regulatory issues, this also shows a full spectrum here. The first comment, IRB created COVID-19 specific review boards to expedite the numerous requests. And then you can see a contrasting approach for an institutional. For some time, the IRB was only reviewing COVID related studies, with the implication being all the other work was getting held up.

And then finally, this respondent you can take from the context that they refer to the research ethics board, so

it's not in the U.S. The challenges have been in terms of research ethics board and privacy. Neither of these things are nimble in our jurisdiction, so it took a long time to fulfill requirements and this meant missing out on many COVID patients.

So we really see a lot of different ways institutions are handling the IRB during COVID, and that's impacting the way research is being done in other domains. Next slide.

Okay. So just a little bit of a transition to Sara's talk. We also asked about reuse of non-COVID samples for COVID-related research. And only 24 percent of biobanks reported that they were getting requests for their samples to be utilized for COVID research. They are sort of non-COVID samples.

And, you know, this was a snapshot at one point in time. It may be interesting to see this may increase over time or it may decrease over time. Next slide.

And we had numerous comments on this particular topic of reusing non-COVID samples. And they were all pretty similar. Basically pointing out that the non-COVID-19 samples especially those collected from before the pandemic were being useful or were perceived as useful because they allowed to capture samples collected at a time they knew the people, the donors did not have COVID and had not had COVID, so provided a

type of control for this kind of research. Next slide.

I really just want to take a minute to recognize the task force that worked with us within ISBER on this project. You can see the members here. And I want to particularly point out Marianna Bledsoe and Helen Morrin who really were with us from the very beginning of this conversation and were champions of this project within ISBER and obviously contributed a lot of intellectual support and ideas to this. So I really, really appreciate their contribution. Next slide.

And I just want to close by highlighting Roselle Ponsaran. So Roselle is at Case Western University and she really from the beginning to the end of this project was the person who made it happen. She built the survey. She really had her hands on the data and helping us get this together. I want to give a big thanks to Roselle.

So next is Dr. Hull.

>> DR. HULL: Thank you. I want to thank the organizers for inviting me to present in today's session on what I believe is the one-year anniversary of when the novel coronavirus was identified in the U.S. press. And as we saw just now from Dr. Brothers's really excellent presentation, this novel coronavirus has affected the conduct of research with biospecimens in a number of ways.

The topic I am going to focus in on required me to

reach back into my public health training to remind myself of tools and ethical frameworks that are tailored to the urgency, seriousness and skill of a public pandemic.

And may lead us to different conclusions and decisions we make in a typical day. Next I am required to tell you these are my views, not necessarily those of the government agencies that employ me.

At the same time, I have to acknowledge that this is based on a collaborative effort, manuscript that has been accepted for publication that I hope will be coming out next year and the names of my coauthors are listed here. So I am really indebted to them for the opportunity to develop these views in collaboration with really smart people. Next slide.

My colleagues and I started thinking hard about these questions when a story about the Seattle flu study broke in *The New York Times* back in March of last year. Study researchers had already been collecting samples from people in the region with flu-like symptoms. Travelers to the Seattle area early on.

The researchers realized in late January they had an opportunity to rapidly test their biospecimens for COVID-19 to ascertain whether community spread had already begun. But their plans were met with bureaucrat resistance from state and federal officials, even though the IRB was supportive of different components of their plans.

And even though the team did decide to go ahead and run the tests and, in fact, they did eventually find evidence of sustained community transmission, they might have been able to do so weeks earlier had they not run into these delays. And they were ordered to stop this testing of existing specimens and then eventually were only permitted to proceed with collected samples with specific consent.

And among the concerns that were flagged was this, by officials was this lack of explicit consent for the future research use of the specimens they had collected for a different purpose. This case struck us as a misfire, as a missed opportunity to gain very important information at a time when we still knew almost nothing about the epidemiology of COVID-19. Next slide, please.

So we thought it would be useful to take a step back and analyze this kind of repurposing case carefully, asking whether, for example, in an emerging infectious disease pandemic, is it ethically acceptable to repurpose researched biospecimens for a reason other than the original one that motivated their collection and under the original consent?

Stated a little differently, does an emergency situation justify prioritizing the benefit of advancing population health at the expense of familiar protections for individual human research subjects? Next slide. I do want to be clear that our intent here was not to interrogate the

Seattle flu study case specifically, but rather to use that as a jumping off point to identify and analyze the broader issues raised by this kind of a case.

So that the next time this comes up, IRBs, researchers, public health officials, won't be taken by surprise. They will have some arguments that they can draw upon under pressure. Next slide. So the claim that we make is that it can be ethically appropriate for researchers and public health authorities to use previously collected identifiable research specimens for a pandemic-related purpose even if the underlying consent would not otherwise permit that use under certain conditions.

And this claim requires us to bridge research ethics with public health ethics which are two distinct but related networks.

Next slide.

A limited set of activities to which this claim will apply. When the threat to the public's health is sufficiently high and urgent, and when we are confident that the proposed activity will help to address this threat is going to be done in a methodologically rigorous manner and there's really no other way to get this important information in a timely manner.

So there has to be an element of uniqueness to using these particular samples. So when we are talking about

retaining identifiers, for example, we are assuming that this only applies in cases, this is only in cases when it's vitally important to do so for maximizing the public health value of these samples. Next slide.

To my knowledge, there hasn't been any rigorous analysis of these questions, but we do have precedent available to us in a number of well-documented related samples where it's widely agreed that we can relax norms and impose constraints on individual autonomy to advance other weighty goals like promoting the public's health. And in our paper, we borrow from these four examples as reference points for how we can make tradeoffs in not-ideal circumstances between individual and more community-focused principles. Next slide. For example, we are all pretty familiar by now with measures like mandatory vaccination, quarantine, masks, contact tracing for which there is broad agreement that when we are living in the midst of a serious pandemic it's ethically acceptable for the state to restrict liberties and override the autonomy of individual to prevent harm and protect the health of communities. Next slide.

So these cases rely on a public health ethics framework that's nicely laid out in the chapters of this Oxford handbook of Public Health Ethics that's pictured here which was edited by three of the best mentors that a bioethicist could ever hope for. So an analysis of the ethics

of a public health action requires us to ensure that it will promote the health of the population.

We have to figure out and ethically distribute the actions, benefits, and burdens, and we have to pick the least restrictive measures needed to achieve the identified public health goals while respecting autonomy to the greatest extent that we can under these circumstances. So just to apply this framework to the present repurposing case, we would have to argue that repurposing biospecimens to facilitate early surveillance, for example, promotes public health because it can inform the strategies that public health officials use to limit transmission of the disease. Next slide.

The framework is also going to require us to look closely at the relevant resistance associated with a given action. And so when we look at risks to individuals of repurposing their research specimens, we are talking about things like risks to their confidentiality and the harms that may go along with re-identification, as well as their interest in ensuring that the kind of research that's done with their samples is consistent with their values.

In the paper we argue that these concerns are relatively low and we are more comfortable overriding these interests in cases where we don't have strong evidence that secondary research goes against patient or participant values, especially when we weigh this against the important public

health goals that we've already identified. Next slide.

I don't think the concerns about risks to groups are as easy to dismiss. There is precedent for having justice and fairness concerns, of course in the context of using biospecimens, especially without explicit consent for specific future uses. And we are especially concerned about cases in which repurposing samples runs the risk of burdening certain groups disproportionately.

And in the paper we contemplate instances in which one group's resources are exploited to benefit another group. Opportunity costs associated with redirecting a community's valuable resources that could have been used in other beneficial ways for that community or that could lead to stigmatization of the populations who become identified with results. Next slide.

And so we propose steps that can be taken to mitigate these risks such as reported data without group identifiers, engaging with communities to let them know what's going on with the proposed research is to get their input on the design and conduct of the research as well as dissemination and implementation of results, and importantly monitoring the issue over time and making course corrections as needed. Next slide.

As an example of what this kind of engagement might look like, the All of Us program at the NIH realized it had

samples, it had collected samples in the right time frame that it could test for the presence of coronavirus antibodies, and this case isn't exactly analogous to the Seattle flu study. It was believed this research still could provide important public health information maybe even helping to further pinpoint when coronavirus entered the U.S.

But the program also acknowledged there was potential for stigmatization especially when reporting the findings by group identifiers. The program convened a rapid response tribal consultation to consider whether samples collected from participants who self-identified as American Indian or Alaska Native. That's what that acronym in my slide means, could be used for this seroprevalence study.

This ultimately lead to a decision not to use these samples at this time because it was realized that the risks would indeed outweigh the benefits to tribal communities as a whole. And doing so also risks subverting a fuller tribal concentration process that was already being undertaken by the program. So again, although this isn't exactly analogous to repurposing as I defined it for our discussion, I take this as a hopeful sign of the potential model to ensure that such processes -- to ensure we mitigate the risk of group harms in other cases. Just to recap, next slide, please. When investigating an emerging pandemic may push public health officials and others, and IRBs -- fall outside our normal

mechanisms and we conclude identifiable research specimens in this kind of an emergency situation can be identified, can be justified under a robust public health ethics framework to guide the circumstances under which such decisions are ethically supportable. Next slide. I want to give a quick nod to other papers that have come out recently that focus on other important aspects of these decisions related to, for example, how we can improve the consent process prospectively and let participants know about potential uses of their biospecimens for public health surveillance, as well as thinking about how IRBs should apply consent waiver criteria in the context of a pandemic.

I forgot to include the names of the author, it's Dave Wendler and Ben Berkman on the slide.

I want to acknowledge my collaborators from the University of Washington and the NIH as well as a number of people who have given us excellent critical feedback on these ideas, thank you.

>> DR. GOLDENBERG: Wonderful. Thank you so much, Dr. Hull and Dr. Brothers, for those great remarks, those great talks. Just want to remind everyone that the video for these talks will be available on ELSIhub.org after. So if you wanted to go back and watch these presentations or share them with colleagues, please do that. We have some good amount of time for some discussion and we have had some great questions

coming in to the Q&A and into the chat.

Just a reminder if you do have a question, to put it into the Q&A. And I am actually going to start with one that ended up in the chat, but directly relates to something you were just talking about, Dr. Hull, which is the complexities or the recommendations for how we might move forward with consent, broad consent, and whether or not you and your team have been thinking about whether a new element of consent or a new notification in a broad consent framework.

We just went through a lot of changes to broad consent and broad consent elements that might inform participants or potential participants of this potential use in infectious disease.

>> DR. HULL: Yeah.

>> DR. GOLDENBERG: Consent frameworks.

>> DR. HULL: I definitely endorse that idea. I think that I believe in our intramural program we already added in some language that points to potential public health surveillance uses. Now it's in boilerplate on the last page and whether participants read that is another question.

But I think we ought to be mindful if we are trying to tell people about potential future uses, given that this may deviate from what we normally think about the kinds of topics, it still falls broadly under the umbrella of health-related research. But I think it's a great idea. And

this is really what Ben Berkman and David Wendler, the authors were first, but I think this is what they take on in that paper that I shared and discuss that more fully.

But I don't see any reason not to do that. I still think we may come upon really unique collections of specimens where that wasn't anticipated and it's really that unique niche that we were trying to carve out and give guidance on.

>> DR. GOLDENBERG: Wonderful thank you. And this actually related to a question that came in for Dr. Brothers about consent and about whether or not in our research there were any organizations talk about the need to discuss rules around separating consent for clinical participation versus research participation given the strain of PPE, given some of the things we heard from some of the challenges from biobanks.

>> DR. BROTHERS: Yeah. I don't think we've looked at any consents yet, Aaron. I'm looking at you. You may know as well. I don't think anyone has addressed that explicitly. As we dig a little bit deeper, we may find some things, but I don't think we can say much about that right now.

>> DR. GOLDENBERG: I do know many of the banks that responded talked just about, just maintaining operations due to PPE shortages. So it will be interesting to look a little bit more in depth at, you know, what that, you know, what that, you know, might look like.

>> DR. BROTHERS: Yeah.

>> DR. GOLDENBERG: All right. We have a question for Sara. For the All of Us example that you put forth, were any groups other than AI/AN consulted about repurposing their samples? Do you know whether what was decided if no other groups were consulted, do you know why not?

>> DR. HULL: It's a great and very important question. I'm not -- I wasn't directly involved with these efforts, I have to say. But I know that the program is endeavoring to engage with many other groups over the course of this study and that this is in many ways built into the design. But I actually don't know specifically for this very, for this seroprevalence study.

Rapid tribal consultation, I'm not aware of what was happening with other groups at the time and if this was necessary.

>> DR. GOLDENBERG: You have another question from an attendee. Is there a case for waiving consent in non-COVID research to address other public health emergencies of unequal ancestry or presentation biobanks and health disparities in genomics medicine generally utilizing the few whole population represented data sets that are available? This kind of gets to Kyle Brothers's point earlier about are there lessons that we are learning now from what's going on that we might be able to carry over no other areas that were lacking biobanking research?

I think this might be a good time to chat about those issues. If either of you would like to start.

>> DR. BROTHERS: Sara, do you want to talk about that?

>> DR. HULL: Sure. I absolutely think there can be a case for waiving consent. And, in fact, I believe, I am going to go back to what I understand of the Seattle flu study case. I believe the IRB in that case did believe that these activities met the criteria for a waiver of consent. And in the paper we discussed that as well.

But I think to the extent that we have evidence that the use wouldn't conflict with participant values, I mean, we know there are a number of criteria. I think frankly, I don't think it's that much of a stretch for people who have consented to a study involving a respiratory-born illness to think about those being repurposed for something else. It has to be analyzed on a case-by-case basis, of course, but there are a number of cases where those criteria would likely be met with a careful analysis by an IRB.

>> DR. BROTHERS: Agreed. I think, this audience is very familiar with the tension in this particular question about, you know, if a group is underrepresented in research and then sort of do an end run around consent to better represent that group, there could obviously be a scientific and hopefully down the line a societal and health benefit to

that group by doing so.

But at the same time part of the problem from the beginning has been, you know, not treating populations, you know, the way that they deserve to be treated. And so I think there could certainly introduce a problem where you sort of are trying to do something helpful, but at the same time you are sort of further compromising the efforts to build trust. So I think there's definitely a balance to be struck there.

>> DR. GOLDENBERG: Another question from an attendee. Can you please clarify the challenges that are unique to repurposing samples for biomarker research versus genetic research related to COVID. Could autonomy be overwritten when considering genetic research? I guess this is a question about does the kind of research itself make a difference in thinking about these kinds of considerations?

>> DR. HULL: I can start with that. I don't know, Kyle, if you have anything to add. But yes, I mean, I do think that kind of research is very important. I think if we are talking about sequencing the pathogen and getting samples so that we can pin that down in a very urgent type of a situation, it's different than longer-term studies that are doing genetic analysis to follow people over time.

And I think at some point it's going to flip to the presumption that we ought to follow our normal practices related to informed consent. And that includes thinking about

how those results will be used, whether they will be shared with participants, whether we are talking about populations that we already know well are going to have concerns and have potential for stigma and harm attached to them.

So we would want to do a very careful analysis to talk about whether the genetic analysis is serving some important public health goal that can't be met any other way versus longitudinal research that can be done under a more extended oversight kind of a framework.

>> DR. BROTHERS: Yeah, I would very much agree with you, Sara. And I think there's another distinction to be had between sort of research that's in the zone of what was the original consent and vision, and then research that's very much not. So, you know, one distinction I might make is something like if a researcher or if a donor, a participant is in a health context in a healthcare system is asked to donate a sample for some specific scientific purpose but the clear understanding is that's a health-related purpose, then I think you could really make a relatively straightforward case that other types of health-related research could still be, you know, you could make a case for using the samples even if they weren't mentioned in the consent because it's very much along those same lines of what the original consent was for.

But utilizing those samples instead for, you know, research on social factors like educational attainment or

something like that, then, you know, I think that case is much more difficult to make. And so I think the sort of expectations of the donor is really important.

>> DR. GOLDENBERG: That's great. So that actually relates to one of the questions that's been voted up a little bit in our Q&A which is for Sara but I think we Dr. Brothers you might also have some insight. Sash when you say consent would not permit usage for study during a pandemic, do you mean that the consent prohibited such use or is that such usage was not specifically mentioned in the consent?

>> DR. HULL: Yeah, this is a great question and it kind of catches me a little bit in a bind. I generally argue that we should never go against promises that have been made. And so I think, I didn't use my words carefully enough to suggest that what I was envisioning in most circumstances is that consent forms would be silent on those questions.

It's a little hard for me to imagine exactly how a consent form would have specifically precluded or prohibited these uses. I think if it did, I would have to look really closely at what the reasons for that were. And I would probably have to assume that there was a good reason and it was related to a level of community engagement, for example, where that was a very important value that we have to pay attention to.

So I would probably pause if I came upon that kind

of language. And I didn't quite factor that into my comments. I really appreciate that distinction.

>> DR. GOLDENBERG: Wonderful. And the next question is also for you, Dr. Hull. But I think we can kind of talk about it. It says the example of tribal consultation is great, but who and how do you recommend engaging less well organized communities that would have an equal risk for stigmatization? I think Dr. Hull in your talk, you talked about the group harm of stigmatization.

So how do we think about that on a larger level across multiple communities?

>> DR. HULL: It's a great question. We have more formal structures and mandates in place as they pertain to American Indian and Alaska Native populations. And the procedures for consultation are clearer. And that question, the person who asked that question is absolutely right. That's not a model that necessarily applies to other groups where it's very important to do this kind of consultation.

I mean, there's a really robust literature out there about how to do community-based participatory research, how to identify. We've talked about it even in some of the prior Friday Forum sessions here, how to identify ways to reach communities by forging relationships with institutions and groups that are trusted by those communities and working to develop authentic enduring relationships.

I think, I have seen tons of really great chats happening on Facebook with communities around vaccination, which is something that I think is working in this very distanced moment in time. So I do want to also say that I think that it's not something we can pull out of our back pocket at the last minute when we need it. This is something that's incumbent upon researchers and certainly upon us at the NIH to be doing this in a longer-term sustained way so that when emergent issues come up, we have already got the foundations and are working more trustworthy approach to offer from the get-go. So that would be the one thing I would want to add to that.

>> DR. GOLDENBERG: Absolutely. Thank you. We have a couple more questions and a few more minutes. I want to remind everyone we will have at post-forum session for continuing these conversations. And I know is that Dr. Brothers and Dr. Hull will be available as well as some of our other colleagues for that post-forum conversation.

Quite often we have consent options that are either one relevant to the person's health condition, two, genetics, or three, kind of future research not relevant to the person's health condition which covers any future use in infectious disease. Is there any reason more options need to be included? This goes back to our conversations about whether or not a specific consent element needs to be described around

infectious disease.

If either of you would like to take that comment?

>> DR. BROTHERS: Yeah. I would be interested to hear what Dr. Hull thinks. In general this is going along with my earlier comment, there's sort of a distinction between broad consent and universal consent. I think Mildred introduced that idea to me at one point. Dr. Cho.

So, you know, the idea of universal consent, we are going to use your sample for whatever the heck we want to use it for, right. And broad consent is we intend to use your sample for health purposes. And so I personally think that biobanks that have utilized something more restrictive than broad consent to focus on a specific area or on a specific study or something like that, ultimately just end up leading to the kinds of problems that Dr. Hull is talking about.

It could have been anticipated from the beginning that those samples would be used for other purposes, probably at least hindsight is 20/20, I guess. So I would really lean towards a broad use. I think universal consent model is rarely ideal. There are some very narrow circumstances in which you might want to use that.

But I think in general you are better off just explaining to participants that we might use this for lots of different kinds of health purposes.

>> DR. HULL: Yeah, and I would add to that, I sort of

infer from the question, I'm picturing the chat box model of consent. And I'm personally not a fan of using consent forms as datas collection instruments. I endorse completely what Dr. Brothers said and would say that as an instrument rather than granular options, I would like the consent form and the consent process to kind of explain these broader envisioned or now, you know, can't take us by surprise anymore. We have to unanticipated it as Susan Wolfe once said and hover it in a thoughtful meaningful way.

>> DR. GOLDENBERG: Wonderful. I think we have time for one more question. We have one that's been upvoted a few times. How can societal mistrust about data aggregation by big tech be more broadly balanced with the ethical recommendations of justifying repurposing biobank samples without consent?

What steps can be taken by public health researchers and practitioners to cultivate and maintain the public's trust? This could be for either Dr. Brothers or Dr. Hull.

>> DR. BROTHERS: I think it's a great question. I was going to try to cover for Dr. Hull.

(Laughter)

>> DR. BROTHERS: Yeah, I would love to hear what you think, Dr. Hull.

>> DR. HULL: So sorry. I actually missed the very

first part of the question. I take it, it had to do with being involved with commercial entities?

>> DR. GOLDENBERG: Thinking about the potential mistrust on the parts of potential participants who are worried about the use of their data either aggregated or not, and what kinds of recommendations might we make to protect must be's trust or promote public trust at the same time utilize the data effectively.

>> DR. BROTHERS: Sort of like what makes it okay for us to do it and not them?

>> DR. HULL: So I think this is a problem that consent alone isn't going to be able to address. And it goes back to my idea that trustworthiness is a process that is sort of on us as researchers, and as entities that support research to really, the burden of proof and transparency. We need to explain how this works if there are public/private partnerships, we need to be very clear about how we share data, how it's used, who does profit and who doesn't. I mean, that's a form of disclosure. But it's really a broader conversation that doesn't just pertain to this context. But a much bigger challenge that needs to pervade all of the work that we do.

>> DR. GOLDENBERG: All right. We still have a couple more minutes to look at a few other times -- a few other questions that have been raised. This is one that came in

very early on. Given that for surveillance we can use wastewater, would it not be more appropriate for pandemic surveillance to reduce PPE, time money and individual consent or is the idea that when the case rate is very low, how do we make decisions of how we actually think about what samples we are using and not using?

If any of you have any thoughts about that.

>> DR. HULL: Yeah. This requires us to have the right expertise at the table. And I think for any one study, I definitely glossed over making the case for what a rigorous example, the bar for what, how we review the science is quite high. And we have to have the right people at the table when making these decisions.

So bioethicists are going to have to partner with infectious disease experts and epidemiologists and IRBs ad hoc at the table is going to be an important element of this. I can't answer that exact question other than to say scientific review and the robustness of the proposal is a really critical element that we elevate in our argument that can't be understated.

>> DR. GOLDENBERG: Kyle, I don't know if you want to state anything. But we saw in our work, you know, a little bit of discussions of the biobanks that we talked with about the kinds of studies that are being asked for and there's kind of a wide range. But I think getting into more of the what

kinds of specific questions are being asked of the data will be really important.

>> DR. BROTHERS: Yeah. And there was a question actually Marianna asked, Marianna Bledsoe asked the question, what about, you know, biobanks now collecting COVID samples getting more requests? I think that was the underlying question there. I looked it up on our spreadsheet, and of the biobanks collecting only non-COVID samples, five reported, there were 40 of those, five of them reported they were getting requests for COVID for uses.

And of the biobanks that are collecting both COVID and non-COVID samples, there are 41 of those, 13 of them said they were getting requests for use of their samples for COVID. So I think it's pointing to some biobanks that may be more tied in with the COVID community and are really working with that group.

>> DR. GOLDENBERG: Wonderful. Well, I want to thank Dr. Hull and Dr. Brothers again for wonderful talks. The I'm sorry we didn't get to everyone's question. If you can, if you would like to, we invite you to join us over in the afterpanel Zoom and continue this conversation. I want to thank everyone for their thoughtful questions and discussion.

This was a really wonderful session. And I know we will be continuing some of these conversations next month when we talk about infectious disease genomics and COVID a bit

more. So I invite you all to come back next month and continue this conversation. So thank you, all very much. We hope to see many of you on the panel discussion after the session, and just to remind you, it's in the chat.

It's also been sent to people who had signed up in your e-mail as well. So hope to see many of you over there. Have a wonderful weekend and thank you, all so much.