

WEBVTT

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Stephanie Kraft: hi my name is stephanie craft i'm an assistant professor of bioethics at the University of Washington school of medicine and Seattle children's research institute.

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Stephanie Kraft: And i'm pleased to be sharing this talk with you today as part of the spring 2021 llc conversation series.

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Stephanie Kraft: Today we'll be exploring the question, what does respect for persons really mean and i'll be discussing some practical considerations for demonstrating respect in genomics research.

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Stephanie Kraft: Respect for persons is a foundational principle in bioethics, and it cuts across everything that we do in clinical care.

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Stephanie Kraft: In research and really in every interaction that we have with one another, whether in a professional setting or in a personal setting.

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Stephanie Kraft: We all know each other, a responsibility to to treat one another with respect and that stems from our right as individuals and as human beings to be treated with respect, and to be recognized as individuals.

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Stephanie Kraft: Now this responsibility to to demonstrate respect it is heightened in the context of research, where researchers are asking participants to take on.

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Stephanie Kraft: burdens and risks, above and beyond what they normally would for the potential benefit of others and so it's really important in this context to understand very clearly what we mean by by showing respect for persons and how exactly we do that.

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Stephanie Kraft: Now the the belmont report which, which is a foundational research ethics guidance document in the United States identify that respect for persons that's one of the three key ethical principles that underlies.

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Stephanie Kraft: Our protections for a human research subjects, the belmont report, it talks about respect for persons in terms of two key ethical convictions, first, that we should be treating individuals as autonomous agents and, second, that people with diminished autonomy, are entitled to protection.

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Stephanie Kraft: And in the year sense the belmont report was was first.

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Stephanie Kraft: was first written, there have been there's been a lot of conversation, and a lot of scholarly writing about.

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Stephanie Kraft: much broader conception of respect for persons that goes above and beyond simply promoting autonomy and protecting those with limited autonomy.

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Stephanie Kraft: That maybe includes autonomy, but but addresses other obligations that we might go to one another, that fall into that we owe to research participants in particular.

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Stephanie Kraft: That might fall under this umbrella of what it means to show respect for persons one of those writers, that I particularly find helpful is one by Neil dicker it from a little bit more than 10 years ago, who in writing about what it means to show respect for research participants.

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00:02:24.150 --> 00:02:34.770

Stephanie Kraft: Rights that first we need to appreciate a person with value Second, we need to recognize the demands of value places on our behavior and Third, we need to act consistently with that recognition.

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00:02:36.180 --> 00:02:47.070

Stephanie Kraft: And so it's this last point that I want to focus on for the remainder of my time today and explore the question of what it means to act consistently with that recognition, or in other words what actions.

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Stephanie Kraft: Do we need to take in order to effectively and meaningfully show respect for research participants.

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Stephanie Kraft: And we, we know we know that respect to do stems from the individual value that that each person has, but that it manifests through the relationships that we have with one another.

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Stephanie Kraft: And, and all the various factors that play into those relationships both interpersonal and more more broadly on a systems level.

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Stephanie Kraft: And so it's really important to be exploring the variety of different ways, through which we can be conveying respect for research participants throughout all of those.

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Stephanie Kraft: interactions and all of the decisions that might be made in a research, study that could contribute to participants experiences of respect.

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Stephanie Kraft: And it's really important that we, that we do that and we focus on the participant experience of respect because.

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00:03:34.170 --> 00:03:48.990

Stephanie Kraft: If a participant is not experiencing respect, even if we think that we are conveying respect and that we are treating people with respect, and I would argue that we're not fulfilling our ethical obligation if we're not actually respecting people in a way that feels respectful to that.

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Stephanie Kraft: And so that's precisely the question that I thought to explore in the study that i'm going to share with you today, which is what.

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Stephanie Kraft: conveys respect what actions in a research, study are are perceived of respectful by research participants, so this is a question that has only been explored, a very small small amount didn't.

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Stephanie Kraft: Not a lot in the context of research and particularly genomic research so to learn more about what participants perceived as respectful my team and I conducted a exploratory qualitative interviews study.

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Stephanie Kraft: With research participants to find out what some of those things are we conducted a series of interviews with participants in a clinical genetics implementation studied notice the charm study.

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Stephanie Kraft: Very briefly, the charm study enrolled primary care patients who were at heightened risk of hereditary cancer based at to clinical sites that serve diverse patient populations.

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Stephanie Kraft: charm participants were offered clinical excellence sequencing for hereditary cancer syndromes as well as additional findings and carrier findings.

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Stephanie Kraft: And they enrolled through a web based family history screening enrollment process which could be done either in clinic or remotely.

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Stephanie Kraft: They submitted a saliva sample by mail and then received their genetic testing results on a phone call with a study genetic counselor or, in some cases by a letter from a genetic counselor.

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Stephanie Kraft: In addition to these activities participants also were invited to complete a series of surveys and some participants were invited to complete qualitative interviews.

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Stephanie Kraft: Our interview studied involved a series of roughly 30 to 45 minute long phone interviews with participants.

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Stephanie Kraft: And we use a semi structured interview guide that asked participants to reflect on their experiences of feeling respected or not respected in the medical setting.

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Stephanie Kraft: In the research setting and then also how they connected their experiences of respect to their feelings of trust in healthcare and research and their decision to enroll in research.

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Stephanie Kraft: We analyze our data using a descriptive content analysis approach, where we started with a we developed a code book based on inductive and.

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Stephanie Kraft: deductive coding techniques and we then systematically coded all of our interview transcripts We then identified the codes that related to respect in the research studying in particular we summarize those and discuss how they related to one another as a author team.

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Stephanie Kraft: And those are the findings that I that i'm going to share with you today, focusing on the set of activities and domains, through which participants perceive respected research.

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Stephanie Kraft: We interviewed a total of 40 participants 30 participants primarily spoke English and 10 spoke Spanish, as you can see, the majority of our participants identified as female.

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Stephanie Kraft: Most either reported Hispanic or next or white or European, American race or ethnicity and, as you can see, there was a fairly broad range of educational attainment and annual income, both of which word self reported.

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Stephanie Kraft: Our participants identified four key domains of respect and research their personal study team interactions.

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Stephanie Kraft: Communication processes, inclusion and consent and authorization and i'll walk through each of these in turn, I also want to point you to our recently published article in the journal of medical ethics that talks a bit more about these and a bit more about our study.

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Stephanie Kraft: So the first domain that our participants identified was personal study team interactions.

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Stephanie Kraft: And here participants really focused on that one on one interaction with somebody from the study team, whether that was by phone or in person.

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Stephanie Kraft: They really emphasize the importance of feeling like that person approached them and treated them with empathy that they cared about them and actually listened to them and they gave them the time to to really have a meaningful conversation.

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Stephanie Kraft: They also talked about the importance of feeling appreciated and how, when the study to emphasize the the potential ways that their contributions, could benefit not just themselves, but others across society and and science more generally.

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Stephanie Kraft: Many participants pointed to that is feeling respectful as a feeling that their contributions to science to society will be recognized.

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Stephanie Kraft: and others pointed to the study staff being non judgmental and that's what's, particularly in the context of a study, where the staff might be collecting.

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Stephanie Kraft: Family history, information and sensitive medical information, or in other cases participants spoke about the importance of non judgment of non judgment.

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Stephanie Kraft: When a when they might have had questions about the study and they felt like they could ask the study staff any questions that they had and wouldn't be made to feel like you know there they had there was a stupid question or a bad question anyway one participant summed up.

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00:08:29.730 --> 00:08:39.510

Stephanie Kraft: Some some this this domain up nicely and said that, for me it comes down to how they treat me they don't treat me like a patient they don't treat me, like a number they treat me like a person.

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00:08:41.460 --> 00:08:47.160

Stephanie Kraft: The second domain that our participants identified was communication processes and here participants were really focusing on.

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Stephanie Kraft: The procedures and processes in place for making sure that the study team as a whole was communicating in a clear and consistent manner with with participants.

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Stephanie Kraft: So some some folks talked about the importance of having multiple options for communication that they could reach the study team by phone or by email, and they somebody was always responsive to them.

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Stephanie Kraft: That when they reached out they got a response that they somebody answered the phone or reply to their email for the week quickly.

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Stephanie Kraft: They also talked about follow up along similar lines that purchase that the study staff was proactive and reaching out to them and that they actually followed through on their promises and one of these was the promise to share results with them.

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00:09:28.530 --> 00:09:36.450

Stephanie Kraft: So that they they were told that they would receive results up front and then they actually did receive those results at the end of the EPI throughout the study.

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00:09:37.890 --> 00:09:47.280

Stephanie Kraft: One participant spoke about this said that leaving you not knowing what happened, what didn't happen, where I have to call to know if they don't call you, I think that is disrespectful.

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00:09:49.500 --> 00:09:55.470

Stephanie Kraft: The third domain that our participants identified was inclusion and here participants talked both about feeling included themselves.

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Stephanie Kraft: and recognizing the efforts at the study team was making to include others beyond themselves.

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Stephanie Kraft: So some folks talking about noticing the clear efforts of the study was making to include people from diverse backgrounds, and so this included.

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Stephanie Kraft: Having the study materials available and having to study staff available, who could speak both English and Spanish they talked about reaching out to clinics that didn't often have research available to them in the past and really making this a primary focus of of the goals of the study.

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Stephanie Kraft: They also talked about the the study materials being understandable and being accessible to two people regardless of their level of regardless of their comfort reading complex medical materials.

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Stephanie Kraft: And they also talked about the importance of having procedures that were accessible, so, in some cases, this.

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Stephanie Kraft: This referred to the ability to complete the entire study remotely some people talked about having having jobs that required them to work or that that they could that they couldn't get away from during business hours or.

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Stephanie Kraft: Childcare obligations and so that they could they could participate in the study, even outside of those regular business hours.

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Stephanie Kraft: Because it was able to be done remotely another person spoke about having social anxiety and how coming into a clinic to participate, would have been a major barrier and so having this available allowed that person to participate in the study.

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Stephanie Kraft: Conversely, another person spoke about being able to come in and work with the research team and having somebody who helped walk through the.

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Stephanie Kraft: Study procedures with that, so this person said the researchers were willing to work with me as far as where we had to meet up and do the study and really, really meeting the participants where they were in order to to meet whatever needs any individual person had.

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00:11:43.800 --> 00:11:49.920

Stephanie Kraft: Five Finally, our participants also identified consent and authorization as one of the domains, through which they perceived respect.

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00:11:50.160 --> 00:11:55.410

Stephanie Kraft: And so, this fits with our traditional understanding of respect for persons as articulated in the belmont report.

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Stephanie Kraft: of promoting autonomy, but the way that our participants talked about consent and authorization I think went above and beyond simply promoting autonomy.

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00:12:03.900 --> 00:12:16.620

Stephanie Kraft: And particularly they talked about having information presented that to them in a neutral way and having it presented transparently and being open about the information that was relevant information that participants might want to know about the study.

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Stephanie Kraft: Participants talked a lot about having feeling like they were given everything that they that they needed to know, and that they were really that the study team is really trusting them to make the decision that was right for them, and that was something that conveyed respect to participants.

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00:12:31.770 --> 00:12:40.290

Stephanie Kraft: Here participants also talked about the importance of privacy protections and having those laid out clearly and then, of course, having those actually followed through on and the study.

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00:12:42.000 --> 00:12:48.540

Stephanie Kraft: To speak into neutrality, one of our participants said, I felt like it was very neutral it wasn't trying to push you in one direction or the other.

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Stephanie Kraft: And another participant actually compared their experience of going through the consent process in the research, study to their prior experiences in the medical setting.

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Stephanie Kraft: And they said I like that there was a lot of consent, the medical community doesn't always have to have it a straight of fat.

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Stephanie Kraft: And I think this was a really important quote because it highlights that.

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Stephanie Kraft: Although in this particular study, many of the people who who participated has not had much research experience in the past and so hadn't really had a chance to have had bad experiences with research in the past they.

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Stephanie Kraft: Often alluded to negative experiences that they had in the in the healthcare setting.

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Stephanie Kraft: And so having this opportunity being being provided with a thorough consent and being treated with respect, throughout the research enrollment process.

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Stephanie Kraft: was a way of saying you know we're going to do this right in this research, study and we're going to step up where maybe the medical system hasn't always done that in the past.

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00:13:47.670 --> 00:13:53.070

Stephanie Kraft: And so, with that I want to provide a few takeaways based on our findings.

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Stephanie Kraft: In terms of thinking about how we move forward and how we build respectful relationships between research teams and participants.

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Stephanie Kraft: I think our findings illustrate that every interaction that we have with participants, as well as every study design choice.

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Stephanie Kraft: is an opportunity to build a respectful relationship so we're not just talking about those one on one interactions all of those certainly are important.

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00:14:15.930 --> 00:14:27.540

Stephanie Kraft: but also many of the other choices that we make in terms of the overall approach to the research, study all of those things are relevant to how research teams and participants can build those relationships.

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00:14:28.440 --> 00:14:34.950

Stephanie Kraft: So some of the questions we want to be thinking about are whether we're providing research staff with all the tools that they need, and what additional tools might they need.

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00:14:35.670 --> 00:14:47.310

Stephanie Kraft: To to more effectively have those those interactions with participants and then are we making participant communications of study priority, are we really thinking carefully about what processes and procedures are in place.

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00:14:48.420 --> 00:14:55.650

Stephanie Kraft: Have we done everything we can to make sure that the study is inclusive and what additional resources, might we need to make sure that we are being inclusive were.

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00:14:56.130 --> 00:15:06.390

Stephanie Kraft: In and reaching out to participants and meeting them where they are, and then, finally, are we presenting study information in a transparent way and in a clear way to our participants.

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Stephanie Kraft: And I just want to conclude with one final quote about how our participants talk about the relationship between respect and trust or, as I put in parentheses here trust worthiness because I think that's.

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00:15:18.180 --> 00:15:22.350

Stephanie Kraft: What this quote that i'm about to share with you is really focusing on and.

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00:15:22.950 --> 00:15:31.170

Stephanie Kraft: This participant said that you know, I think, without respect without making you feel respected you really can't trust someone or the study without respect there's no trust.

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00:15:31.890 --> 00:15:40.650

Stephanie Kraft: And so I raised us not to suggest that if if a study you know shows respect for a participant in one instance that that will magically.

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00:15:41.430 --> 00:15:53.340

Stephanie Kraft: Make that study the epitome of trustworthiness, but I think it does suggest that, over time, by making sure that we are prioritizing treating participants with respect.

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00:15:53.670 --> 00:16:09.060

Stephanie Kraft: That can help to build up the trustworthiness of that institution or that research, study and that that can be of great value to many participants when they can see that part of that researchers and research studies are really valuing them as individual human beings.

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00:16:10.350 --> 00:16:20.040

Stephanie Kraft: So with that I want to give a big thank you to my study team all by project mentors and my funders and, of course, the organizers of the lc conversations earpiece Thank you very much.