**Translational Health Sciences – 'Justice and the Egalitarian Research Imperative' Transcript**

Welcome everybody to this to this special public website.

0:00

It's it's a great honour to be to be doing this and to be introducing us.

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I would say a little bit about actually just a second, but I first want to explain this sort of the way in which we want to conduct this review.

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So for information being so, the talk is being recorded.

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And so Robyn has set the cameras and mikes to muted, except thankfully, mine and Alex as well.

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Thankfully, I presume you, Nugent, and that will be like that for the duration of the tour and then she will on news people's minds.

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So please continue off a bit further discussion until I call on the while it is so the

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questions are not going to be recorded just so you don't need to worry about that.

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The way in which you will do well will do the questions is if you can type in the chat that you had a question, that's the preferred route.

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And then that will give me a sense of the order and I'll call on you in that order and

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then you can unmute yourself and put your camera on if you want so that we can chat.

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If you prefer me to read out the question and then write it in the chat, and that's that's perfectly acceptable, I'll say this again in just a minute.

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I'm sorry at the end of the end of the tunnel. So it's it's really great that you have it here tonight.

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This afternoon in the US, Verizon, other today, wherever else you are.

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Alex is the caller Al West, professor of ethics and philosophy and the director of the Centre for Ethics and Policy at Carnegie Mellon University.

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He's recently got a lot of attention.

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I think you would describe this as a lot of attention for your paper with Jonathan Karl Kimmelman on against pandemic research exception,

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which read Science in 2020. But he's in the sort of research ethics community and this community very well known and very well thought about.

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So it's great that he's here to talk about his new book. I'll hand it over to Alex.

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Joe, thank you very much.

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All right, well, thank you, Mark, for that generous introduction and for inviting me to be here and also thanks to Robin for all,
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for helping me navigate Microsoft Teams, which I am not really used to doing.
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I try to talk for aim for about 40 minutes or so, and then hopefully that will leave us plenty of time for questions and answers.
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So the topic for the talk today is justice and the egalitarian research imperative and the
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egalitarian research imperative is a sort of a central feature of my book for the common good,
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the philosophical foundations of research ethics that was just published by Oxford University Press.
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And it's it's free and open access.
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The PDF is if you want to download it from Oxford or from my home page, so I'm going to try to do three things today.
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The first is talk about the parochialism of research ethics of Orthodox research ethics where it comes from,
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both mostly conceptually a bit historically, and how it really eviscerate the rule for justice in research ethics.
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And after that first part of the talk, I'll then add, and in the first part,
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I want to show how that has a really pernicious effect on what I'll call the cognitive ecosystem of research ethics,
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which is sort of the way questions get framed what what views are taken as being central,
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what it would require to answer a question, the kinds of concepts the WHO the stakeholders are, who are seen as being central.
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After that early part of the talk, then I'll transition to talking about the egalitarian research imperative,
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and I'll argue that there is a research imperative. There's an imperative to carry out research with humans.
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That's very different from the kind of imperative that you'll see that shaped the the historical origins of research ethics.
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And after that section,
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then I'll talk a little bit about what the implications are of this sort of new approach to the foundations of research ethics.

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So the first part is the origins of this parochialism, as I want to call it.

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So I think it's really important to see that in the United States,

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at least the birth of research ethics was really driven by a reaction against two things.

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So first, there was a shared perception that there is an inherent dilemma at the heart of research with human participants,

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and the fundamental problem was how to navigate this dilemma.

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And there was a fear that an imperative to carry out research that was grounded in a social

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imperative would wind up justifying an abrogation of the rights and interests of individuals.

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So that's what I want to try to show in this first section.

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I'm trying to motivate and persuade you of this idea.

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And then after I do that, we'll see some of the implications of this.

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So part of what I want to say when I argue at length in the book that, you know,

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the conceptual ecosystem of Orthodox research ethics is really narrow.

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It treats research as a kind of private transaction between two main stakeholders, researchers and study participants.

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It centres protectionism and paternalism,

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so the be the moral crucible of research ethics takes place at the interface between researchers and participants.

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And the main focus for research ethics in terms of an audience is usually the IRP, whose job it is to kind of paternalistic.

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We manage the relationship between these two stakeholders. It primarily treats research as a kind of functional role.

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That's a role like the doctor patient relationship or like the role of the doctor.

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There's the role of the researcher. So the functional role, it's something that you can take on and that can conflict with other social roles.

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And that really ignores the degree to which research is a social undertaking between a lot of different stakeholders.

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And so we'll see why that's important later on. It also disconnects research from a bunch of larger social purposes.

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Part of how justice then gets disconnected in research from how research ethics sort of is disconnected

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from issues of justice and in particular issues of justice in this larger social context.

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So those those are the themes to keep your eye out for now as I try to persuade you of each of these ideas in this first part.

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So I want to take you back to the the heady days of April 1967.

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You know, it's meeting call about the changing mores of biomedical research held at the American College of Physicians.

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So, you know, this is it. The time right before the institution of the common rule the creation of a common rule in the United States

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when there is disagreement about what the norms should be for governing biomedical and behavioural research.

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And in his opening remarks, the famous researcher, Walsh McDermott, opens with this bombshell.

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He says when the needs of society come into a head on conflict with the rights of an individual, somebody has to play God.

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And the whole point of McDermott's remarks is that society enforces the social good over the individual good in a wide range of contexts,

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and there is an inherent dilemma in research with human subjects.

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We can't both advance the social good and respect the good of the individual, and in that case,

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researchers need to be empowered to advance the social good, even if it comes at the cost of the individual participant.

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So he has this precedent or this sort of, you know, particular quote where he says starting, I suppose, with the Yellow Fever studies in Havana,

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famous set of studies by the renowned American researcher Walter Reed, we have seen large social payoffs from certain experiments in humans.

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And there's no reason to doubt that this process could continue.

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However, then, he says, once this demonstration was made, we could no longer maintain in strict honesty that in a study of disease,

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the interests of the individual are invariably paramount.

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So part of what McDermott is taking, you know,

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in his sights here is the declaration of Helsinki that has as one of its claims that the interests of the individual,

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you know, have to be and the physician's concern for the interests of the individual have to be paramount.

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He says I believe that it's been most unwise to try to extend the principle of a government

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of laws and not of men into areas of such great ethical subtlety as clinical investigation.

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So, McDermott, I give you this as a way of just trying to say there was a view before the institution sort of the

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current before the creation of the current institutions rules and regulations in the United States.

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There was a view that there was a social imperative to carry out research that that

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imperative was grounded in the great social benefits that research could create,

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and it rested on a particular view of the relationship between society and the individual.

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So this is another quote from McDermott. You know, it says society has rights too,

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and it is preferable that the power to enforce these rights over the rights of the individual will be institutionalised.

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And then he talks about how it's important that to ensure the rights of society, an arbitrary judgement must sometimes be made against an individual.

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And this is it takes you back to the the head. The quote that eat the statement that he used to open the conference that researchers should be

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empowered to make that arbitrary judgement sometime in order to advance the right of society.

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Now, part of the problem with the way McDermott frames the issue and and sort of in a certain sense,

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one of the refreshing things about McDermott is that unlike other famous researchers of the day,

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he says the quiet part out loud when a lot of other people are content to kind of beat around the bush.

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But you know, McDermott's comments really echo arguments that we saw at the Nuremberg trial.

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Not that many years earlier, just a few decades earlier. And, you know, in the Nuremberg trials,

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Survation is Robert Salacious had argued the attorney had argued on behalf of one of the defendants, Dr. Carl Brand.

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But there was no meaningful distinction between conscription for military service and research that in each case,

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individual sacrifice is required for the common good.

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And it's not unreasonable to exact even the ultimate sacrifice from a person if that's necessary to advance the greater good.

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There were seven of the 23 defendants at Nuremberg were sentenced to death for crimes against humanity,

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including Carl Brandt, in one of the things that Brandt said. He said science under them in, you know, within science.

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Under the Nazi regime, the demands of society were placed above every individual human being as an entity and this entity,

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the human being, became completely used in the interests of that society.

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So you can sort of see Nuremberg as a repudiation of this idea.

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But of course, you know, the Nuremberg and the Nembhard code had very little indirect influence on sort of the course of research

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and research ethics in the United States up until the period that we're that we're talking about.

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So shortly after McDermott's fiery opening publishes his groundbreaking paper, rightly influential.

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So, you know, I think any most people who take a research ethics class probably have to read at least some, if not all, of this paper.

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And in it, Jonas makes this really fascinating argument.

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He says society easily survives the normal toll of sickness and disease.

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And so as a result, sickness and disease really is a threat to the individual, not to society.

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And so for that reason, Jonas argues, there's no social imperative to carry out research.

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It's a noble private vocation, like being a musician.

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And if you're a musician, you might bring joy and pleasure to the lives of hundreds of thousands or millions of people.

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If you're if you're famous, like Yo-Yo Ma or something like that.

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But it isn't the case that you can use the institutions and the coercive power of society in order to promote this private undertaking.

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In order to avoid the kind of totalitarian consequences that Jonah saw in the position that McDermott was articulating.

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As he wants to demote research from an activity that serves the social,

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the interests of society to an activity that serves the interests of individuals, and that becomes a kind of private, optional undertaking.

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So what you see here now, so what does this piece I keep coming back to?

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So some of you will know this is the front piece two halves as Leviathan. So this is the state, right?

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And in what looks like it's chainmail is actually a little tiny images of individuals who comprise the state.

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So we have two very different views.

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We have the same conception of the relationship between the individual and the state, between individual and the collective.

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But we have two different conceptions now of the relative interests at stake.

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On the one hand, you have McDermott, who says society has rights and it can exact a toll from some of its skin cells as it

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were in order to produce medical progress through research with human participants.

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On the other side, you have Jonas who says, you know, cancer if cancer, heart disease and other organic non-contagious ills,

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especially those tending to strike the old more than the villain,

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continue to exact their toll at the normal rate of incidents, including the toll of private anguish and misery.

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Society can go on flourishing in every way,

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so society has no no concern about the the normal rate of disease that sort of pluck off individuals here and there.

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And so the society doesn't have a legitimate claim to use its coercive force in order to promote the kind of progress that medical research promotes.

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Interestingly, on this position now, if you have a pandemic like we're in now with COVID,

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then it can be the case that if proper functioning of society is endangered,

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then both of these views would line up right then I think then in his article,

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Jonas talked about how it might be the case, then that its emergency powers society can take steps to preserve itself,

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that that fall much more closely into the line that McDermott is running.

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And I suggest later, I think that is also part of a problem here.

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So the onus is paper comes out in 1969, during this time in the United States, the Tuskegee syphilis study is happening.

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This the United States public health study of 400 black men with syphilis, the 200 controls in Alabama.

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It involves deception, denial of treatment. No measures are deployed to stop the spread of a communicable disease that the public

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health service has a social obligation to know to stop the spread and to control.

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In 1969, as a blue ribbon panel that is convened to review the study and with but with all but one dissent votes

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unanimously to continue the study until it breaks into the headlines and and the popular press grab hold of it.

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And the scandal leads to the creation of the National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research,

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and the National Commission is what creates the common rule and the whole set of institutions

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and guidelines and rules that we that that constitute Orthodox research ethics today.

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Actually, the National Commission produced the Belmont report that we'll talk about in a little bit.

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The historical point here is relevant because it shifts the balance almost entirely in favour of Jones's position.

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And a hand in glove now, the work of the National Commission, there's a kind of administrative convenience,

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we want to try to make some rules that would prevent this kind of systematic abuse is as simple and easily as we can.

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And so Jones's philosophical position gives the conceptual philosophical cover

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for this position that's motivated by administrative convenience to some degree.

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So without a social imperative, research is sort of treated now as a kind of optional undertaking.

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And so everything gets focussed on what I call the IRG triangle now.

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So our rulemaking talks about researchers,

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the relationships to participants and how the IRB is going to insert itself in this

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relationship in order to protect participants from abuse at the hands of researchers.

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So this is where you get now in this in this administrative convenience,

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you get research treated as a functional role because we need to know when are

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individuals functioning as physicians and when are they functioning as researchers?

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So we know which set of moral requirements should govern their conduct.

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So, so the, you know,

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the Belmont report and subsequent rulemaking annunciate criteria to distinguish when an individual is occupying one social role rather than another.

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So we talk about, you know, is your purpose to fulfil your fiduciary duty to the patient who's in front of you?

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Or are you trying to gather generalisable data? What are the means that you're using?

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Are you using established effective means to benefit your patient?

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Are you deploying novel interventions under conditions such as randomisation that are designed to evaluate efficacy?

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And then what kind of discretion do you have if you're in this fiduciary role where you're providing treatment?

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You have broad latitude to use your professional judgement to advance the interests of the patient in front of you.

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But if you're if you're in this information generating role, then you're required to secure a prospective research review.

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So part of what this does, though, this this framing of the ethical issues as living within the R.B. Triangle,

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it eviscerates any role for the for the value of justice.

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People, I have I've given talks in places and had people say I didn't realise justice was even a value that was in the Belmont report.

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Is one of the key values in the Belmont report.

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But it's the least well developed and in the conceptual ecosystem of Orthodox research ethics, justice really has no distinctive role to play.

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If you're if you have the background assumption and we're talking about private parties in a way that's

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tacitly disconnected from larger social purposes and from other social institutions other than the IRP,

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then there's not really much work for justice to do. I'd say well.

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It went the wrong direction.

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You might say, well, that's that's a little bit unfair, but we can look at an example from the Belmont report to try to drive this point home.

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You know, so within Belmont, beneficence are justice over the same domain and a certain sense of the bottom line.

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They do effectively the same thing.

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When justice is introduced, we're told Will this is about who ought to receive the benefits of research and bear its burdens.

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And beneficence is ultimately about the distribution of benefits and burdens in research across different individuals.

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That's why it's possible when we're talking about risk benefit,

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that the risks to some individuals can be outweighed by the possibility of benefits that will accrue to other individuals.

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So both of these values are treated as operating over the distribution of benefits and burdens to different individuals.

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Justice, we're told, equals ought to be treated equally.

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That kind of sort of the conceptual definition of justice going back to Aristotle, at least, but there's no specification of the space of equality.

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So we're not told what to what, what space we ought to ensure that people are treated equally in.

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That question is left unanswered in Belmont, except in beneficence.

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That question is answered because you give equal treatment to people in the space of welfare.

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And that's why you're allowed to allow risks to the welfare of people in one group to be offset by welfare to the beneficiaries of research,

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so long as there's enough welfare that that's generated.

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So the point I want to make is even though these view these values.

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And there's really not much content to the value of justice, as it's articulated in Belmont,

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but there's pretty substantial content content to the value of beneficence.

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So now if you take a requirement of justice that's enunciated in the Belmont report.

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Right. So one of them is that, you know,

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that there should be a prohibition on recruiting favoured populations for beneficial research and undesirable populations for risky research.

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Well, if you say that value is grounded in issues of justice,

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the ground is very difficult to explain from the standpoint of justice because they're just

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not that much granularity or texture to the way justice is explained in the Belmont report.

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But you can explain and justify this prohibition on the basis of the two other pillars of Orthodox research ethics, right?

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And as an application of both beneficence and autonomy, because you could say, listen,

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if we draw primarily from marginalised groups for quote unquote risky research,

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well, those are groups that are already more likely to have a higher burden of disease.

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They're already likely to have far fewer resources available to them to manage adverse events that might arise.

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They're more likely to have more precarious health and welfare on a general level.

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And so the outcomes of imposition of risk on marginalised groups are likely to be worse than if you impose the same risk on less marginalised groups.

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So that's a straightforward application of beneficence.
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And then it's far less likely you're far less likely to secure consent from marginalised groups
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for that kind of research in the absence of force fraud or insufficiently informed consent.
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So, you know, all of the things that could be seen as being wrong with disproportionate,
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disproportionately recruiting vulnerable populations can be explained by beneficence and autonomy.
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And it's not really clear what the substance of justice is in Belmont that would provide an alternative explanation.
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We really see the absence of justice then as time goes by, and in the 1990s, you know,
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late '90s and then the subsequent decades when controversies in international research come to the fore.
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So there are three requirements that get articulated as governing international research that there should be an adequate standard of care,
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that that research should be responsiveness to host community health needs and priorities,
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and that there's a duty to provide post-trial access in documents like the C OMS guidelines.
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These these requirements are grounded in the value of justice, but without a substantive account of justice in these space.
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A number of commentators argue that these values seem are these requirements seem arbitrary and unjustified at best.
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And then Alan Wertheimer, in some recent work, has a trenchant argument where he says they're also Pereda inferior.
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They raise the cost of conducting research in low and middle income country populations
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that might benefit from research that doesn't satisfy one or more of these conditions,
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but not conducting research there doesn't make anybody better off.
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So by protecting people, Wertheimer argues, we could be making them worse off just by denying them opportunities to advance some of their interests.
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Even though the research in which they're participating might be relevant to other communities
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where they might get sort of the direct benefits of participation rather than post-trial access,
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and where the standard of care they receive might be much lower than it would be in other places.

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And so I think part of the controversy then that's happened about the norms that ought to govern international

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research is the is a result of the vacuum that was created by grounding these requirements on justice,

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but without having an actual substantive account of justice to do the work that's required.

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You also see now in this in this ecosystem that results, you know, the tolerance for what I've called in other places, self-defeating practises.

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And you really see this with COVID. COVID illustrates this an asymmetric concern.

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The risks that participants might be exposed to in research.

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But then the sort of, you know, there's not an offsetting concern for the widespread tolerance for the use of validated interventions

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out of beneficent intent where that doesn't necessarily translate into beneficial outcomes.

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You know,

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so this is a list of the interventions at the beginning of the pandemic that people thought maybe these things will have some therapeutic effect.

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You know, you see ivermectin here, you see chloroquine and hydroxychloroquine.

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The beginning of the pandemic, Dieter Route, who ran one of the first quite poorly designed studies of hydroxychloroquine.

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In an interview, he says, I'm not going to tell somebody, Listen, today's not your lucky day,

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you're going to be getting the placebo, you're going to be dying, he told the reporter.

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Root said he believes it's unnecessary and unethical. The randomised controlled trials are RCTs of treatments for a deadly infectious disease.

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So what you see here is it's, you know, Root saying, basically it would be unethical for me to deny people hydroxychloroquine.

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But of course, you have other clinicians who think it would be unethical of them to provide

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hydroxychloroquine to patients since its efficacy hasn't been invalidated.

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So you have a social status, the right state of affairs in which some people are getting.

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Some clinicians are providing this intervention. Other clinicians are not providing this intervention,

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but a bunch of people think that that the risks that we would be exposing people to in research

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if we randomise them to those interventions are somehow worse than the default state of affairs,

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of just giving those interventions directly to people without generating the information where we know whether they're efficacious are not.

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You have other instances, you know, so people in the United States know when they ran ads,

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some of the this is the product consortium that was looking at convalescent plasma and in their advertisements,

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they say if you survived COVID 19, then you're the heroes that we need.

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The plasma that's in your blood can literally save lives.

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But we have to act fast, so please donate. So, you know, here are the assertion.

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Basically, I mean, if you go further down on this web page, I took this from, they would say, we all, you know,

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we want you to donate so that we can run some of the studies that might be necessary to evaluate,

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you know, the clinical merits of convalescent plasma. But they're basically telling you in the advertisements, Hey, this can literally save lives.

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Well, if it can, if we already know that, why would we need to run trials and if we need to run trials,

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why are we telling people that this will save your life? And the results, of course, right, are really not very rosy.

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Clinicians used hydroxychloroquine with therapeutic intent on a large scale, but the recovery trial showed that amongst patients with COVID 19,

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those who received hydroxychloroquine didn't have a lower incidence of death at 28 days than those who received usual care.

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They did have a longer hospital duration. And then there were some populations that were more likely to progress to the

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outcomes of mechanical ventilation or death than people in the usual care group.

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Yet things that weren't quite as bad with convalescent plasma in the United States,

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100000 people received convalescent plasma outside the context of a clinical trial.

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But again, recovery says there was no significant difference between convalescent plasma and the usual care group.

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So it didn't seem like it was harmful, but it certainly absorbed the time, energy and resources of a wide range of people.

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For for no clinical benefit. So to summarise in this section, then the the aversion to linking biomedical research to important purposes of the state,

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relegating it to a kind of private activity now that that gets evaluated within the narrow confines of the IRP triangle.

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Results in this ecosystem that has all these problems, you have a narrow set of stakeholders with a narrow focus on one point, right?

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I IRB review is one point in a much larger process where many more stakeholders

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have already made decisions about what the protocol is going to look like,

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what the study is going in, what what questions are going to be asked and answered.

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There's the invisibility. The knowledge that research produces and its relationship to a bunch of social

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systems are basically invisible within this within this cognitive ecosystem,

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other than the idea that there needs to be social value to research a concept that up until very recently was not, well explicated.

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Social institutions are invisible, even though research calls them into action and and the information that it

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generates is supposed to feed back into them and their ability to function.

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There's a keen awareness of risks inside research,

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but a far greater tolerance for unfound practise on a large scale outside of research and no social imperative

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to close knowledge gaps between the health priorities of a community and the ability of the communities,

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its social or health care institutions to meet those needs or to rectify inequalities in the

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ability of those systems to address the health needs of the diverse populations that they serve.

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OK, so so that's the critical part.

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Now I want to talk about, I do want to defend a research imperative, but it's very different from the ones that we've seen before.

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So in the prior debate? This assumption that the common good is really the good of a collective,

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it's the good of society where in several different ways that can be represented as something that's quite distinct from the good of the individual.

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And then what you saw was, yeah, this the state has a right or this collective has a right to progress or know the collective

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doesn't have a right to progress because the collective isn't really harmed by sickness,

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injury and disease. Only individuals are.

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So part of what I argued for in the book is that there's just a fundamentally different way of conceiving of the

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common good so that rather than putting the collective on one side and the individual on the other and then debating,

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you know, whose interests are are are paramount, we should see the common good.

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And I think there's also a very I try to argue there's a long tradition of for for views like this,

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the common good as a set of what I call basic interests,

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a set of interests that all persons share in being able to develop and exercise the intellectual

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and effective and social and physical capabilities that they require to formulate,

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pursue and revise a meaningful life plan.

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So in that sense, you know, in a diverse, free, open society, people will pursue a lot of different First Order life plans, right?

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They want to be musicians or scientists or, you know, or occupy a bunch of different occupations or pursue faith traditions and so on.

34:59

Those are part of the first order conception of the good that they want to advance.

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And we they differ in very many ways as a result,

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but they share in common they are what Rawls calls the highest order interest in being able to formulate, pursue and revise a life plan.

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And that is an interest that's common to all of the persons in such a community.

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We in a just social order. Institutions of society have to function in order to secure the common good in this new or in this other sense.

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In other words, the basic institutions of society have to function to secure for each person their basic interest in being able to formulate,

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pursue and revise a life plan. And so basic interests now can be threatened by a wider range of things.

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Sickness, injury and disease threaten people's ability to the cognitive,

36:00

affective or physical abilities that they need to pursue some reasonable life plan.

36:06

So do poverty and ignorance, prejudice, animus and lots of other things.

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So for our purposes, I'll stick to sickness, injury and disease.

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But this is why, right? The effect of sickness, injury and disease on this shared interest and this shared interest as being sort of the

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focus of what a just society is supposed to help secure for individuals is what grounds

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now a notion of justice that takes research away out of the sphere of a private activity

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and puts it in the sphere of social activity that produces a unique public good.

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So this is a unique public good because research with humans is often the only way to generate the information that we need to

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bridge gaps between the ability of individuals to function in this basic way and the capacity of health related social systems,

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public health, individual health live close to client health system to function in ways that will

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safeguard and support and advance those those abilities of individuals effectively,

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efficiently but also equitably. So in order to be able to do that in order for health systems to be able to effectively,

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efficiently and equitably advance the basic interests of people in those communities, we have to understand the aetiology of disease.

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We have to understand the disease mechanisms so that we can intervene on it to try to prevent the spread,

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to try to manage this disease spread or progression of disease,

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or provide treatment to patients to either cure them or mitigate morbidity and mortality.

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So this is the the the first part of the social imperative that social institutions
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of a just state have to secure the life and liberty and welfare of their members.
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The feeling that function in the face of uncertainty requires the knowledge necessary to safeguard health and to make equitable,
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efficient and effective use of the wide range of social resources that go into creating the social systems that fulfil this function.
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And so, you know, a central claim of the book is that there's an imperative to conduct research that closes these
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knowledge gaps that will enable health systems to secure the basic interests of community members.
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So in that sense, for there is a sense which I'm arguing for a claim that that fell out of fashion after the work of the National Commission.
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But I want to be extremely clear lots of the people who flirt with this idea also fall into the very, you know, dichotomy that McDermott postulated,
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and they come very close to basically saying, yes, it's like, you know, society can exact these tremendous, tremendous toll from individuals.
39:03

And I want to say, no, this social imperative does not licence domination in a just social order.
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Basic institutions of society must function to secure the common good, i.e. each person's basic interests.
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And so now we have to think of research not as a social role,
39:26

but as a scheme of mutual cooperation that is just one element within this much larger social division of labour.
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So research is an activity that gets extended across time. It involves multiple stakeholders.
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It calls into action various social institutions, whether they're funding institutions, regulatory institutions, health care, providing institutions.
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And it also generates the information it feeds back into those institutions and shapes their ability to function.
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So the second part of the social imperative, this isn't an external constraint on that first imperative.
40:02

It's an implication, internal implication of that imperative at understanding research as a social,
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as a scheme of social cooperation that must be organised on terms that respect the status of individuals

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as free and equal means that there's also an imperative to sure to ensure that it's a voluntary

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undertaking undertaken with free and informed consent in the same way that society requires the

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widespread participation of people who occupy many different social roles like voluntary firefighters,

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paramedics and other people.

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We want to organise the role of study participant in the same way a voluntary pathway through which people can make a contribution to the common good.

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Part of the way that we secure the credible assurance those people that they won't be

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an arbitrary decision made against them in order to advance the common good to use.

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McDermott's phrase is you have prospective review to eliminate unnecessary risk to ensure an appropriate baseline

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of care is provided within medical research and also have provisions that prohibit domination and abuse.

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So, so this point I was making free societies require many social functions to fill in the important social obligations, right?

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We need teachers. We can't get rid of ignorance. We can't combat ignorance without teachers.

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We need physicians. We need researchers,

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many volunteer firefighters and paramedics in all these people that provide important social services on which our health and welfare depend.

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And then what we do is we try to shape those social institutions so that individuals can see that social role as an avenue

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through which they can advance their own first order of conception of the common good and as a way that in doing that,

41:55

they can contribute to the common good. And so it's a direct implication of this way of thinking about the research imperative.

42:02

The research participation has to be organised research parties.

42:10

Yeah. On this same idea.

42:13

Shape the role of research participation as something where people can see it as an avenue to contribute to the common good.

42:18

Without necessarily making themselves vulnerable to the kind of domination and abuse that McDermott thought was essential and inevitable.

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It's true there are a lot of thorny issues in research where you might say, Well,

42:39

you know, what does that mean in terms of the way we think about research risk?

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I'm not going to go into that here. So there are two long chapters in the book.

42:48

But, you know, I argue in the book that, you know,

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there's for a framework for evaluating risk that satisfies a bunch of really stringent ethical principles that can ensure social value,

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equal concern for individuals, equal concern for the welfare of people inside and outside of these trials,

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and a prohibition against impermissible gambles where basically impermissible gambles are the sort of thing where you say,

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If I'm not allowed to do something directly to you,

43:17

I shouldn't be able to make it permissible for me to do that by just reducing the probability that the same outcome would occur to you.

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OK, so I'm almost done, and now we can talk about, you know, we had a larger conversation.

43:29

But I wanted to say something about what the implications are then for for the field.

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So if you think about international research as an example, now,

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these common requirements from the OMS guidelines that really didn't have a clear normative foundation now have a much more solid foundation.

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The responsiveness requirement is itself a direct requirement of justice.

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You research must be responsive to the health needs and priorities of host populations to ensure that research activities produce

44:03

the knowledge that is needed to enhance the ability of the institutions in those communities to understand and address the

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health needs of the people who live in those communities because they have a fundamental moral claim on the basic institutions

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of their society that they should work to advance their fundamental interests in being able to pursue a reasonable life plan.

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The requirement to provide an adequate standard of care. Larry, to respect participants is free and equal.

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They have to be guaranteed a level of care that doesn't fall below what can be attained and sustained for

44:42

them within the set of basic institutions that provide social services to everyone in their community.

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And the requirement for post-trial access is just an implication that if you generate new knowledge,

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it's not going to safeguard the health of anyone unless it is integrated into the social systems that have,

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as their social function, safeguarding the health and welfare of people.

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Another implication of this view is that the IRIB triangle and the traditional view that,

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like people, scholars in research ethics are primarily speaking to researchers or IRB members.

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We have to we have to broaden the set of stakeholders that we are talking to because we have to broaden that are

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the realisation that many different stakeholders make decisions upstream of IRB review and downstream of study,

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study, conduct and study completion that affect responsiveness and and the availability

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of the knowledge and the interventions that are developed within research.

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So funders and sponsors, crows and researchers, maybe they are more typical and host communities and study participants.

45:58

Regulators in IRB members. But, you know, lawmakers set the incentives in terms of patent law.

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Patent protection. IP protection that incentivise private and public actors to invest their time,

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energy and resources in determining which questions and where they put their time, energy and resources.

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So lawmakers and policymakers have to be some sort of a fundamental interlocutor for research

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ethics when it comes to thinking about what the priority research questions ought to be.

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Journal editors and professional societies, health systems, clinicians,

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patients and future researchers may be part of the reason for ensuring the quality of scientific

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research is not about the risks that poor quality research might impose on study participants.

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That's sort of how you have to funnel and frame issues about scientific quality in the sort of the current research ethics ecosystem.

47:05

But, you know, research the information that studies produce is consumed by a wide range of stakeholders,

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health systems, clinicians and future researchers.

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And so they rely on that the quality of that evidence in order to fulfil social obligations that they have.

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So we have to move also away from a protectionist view where the primary function

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of research ethics is protectionism to one where the idea is the primary

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view of research ethics is to ensure that this scheme of social cooperation cannot be co-opted by any particular stakeholder to advance their narrow,

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parochial interests at the expense of the common good. So a lot of stakeholders in in in research engage partly to advance parochial interests.

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Profit promotion, access to novel treatments. The prestige of being a research institution.

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I think it should work to constrain and align these interests as much as possible with the common good, and I've got a long chapter about how.

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Framing the IRP review in protectionist terms,

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disconnects it from some of its actual important functions where it really does work to ensure that the cooperation amongst these

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different stakeholders is is aligned with producing higher quality research as well as protecting the interests of study participants.

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You know, FDA or EMA or other regular, you know, other institutions that set regulatory standards for safety and efficacy choices endpoint in a trial.

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The study design A lot of these questions now pose these questions beyond the confines of the single protocol to the IRP.

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So Jonathan Kimmelman and then Jonathan Kimmelman and I have together have done research

49:07

on portfolio level questions questions that aren't just about individual study protocols,

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but whole sets of study protocols.

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Well, those things become very salient in this wider formulation precisely because they implicate the efficiency with we.

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Research uses scarce resources, including how many people are required in order to answer a question.

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The bandwidth of information that research produces about a question whether that which stakeholder is that information is really useful for.

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And then finally, as I said, law and policymakers need to be a fundamental focus,

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both in terms of how they set domestic research priorities and how we engage in our research, our collaborative research abroad.

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And I think vaccine equity and the fundamental problems that we're having right now

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around vaccine equity sort of shine a light on how this whole ecosystem of we had to.

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We had to answer a novel question. We generated now a new resource.

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And now we've got to carry out the difficult work of equity of making that resource available to all

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of the communities that require it in order to secure the basic interests of their community members.

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So in conclusion, I are you in the critical part of the book that the boundaries of research ethics are arbitrarily narrow.

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A bunch of current requirements seem arbitrary and self-defeating.

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There are a whole raft of stakeholders who exert concrete and real influence on the way research is done,

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but who are basically invisible and whose conduct is invisible within Orthodox research ethics and the relationship of research

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to important social institutions and the moral responsibility of those institutions is far less visible than it ought to be.

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In place of this, I offer a much broader conception of research as a social activity spread across time involving multiple stakeholders.

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It's one element within a much larger division of social labour in this position.

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Issues of justice becomes central.

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Some of the existing requirements that sort of are put forward without solid justifications are given a much more coherent foundation.

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The full range of ethical issues now that are salient to the conduct of research can be

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framed while considering the duties of a much more comprehensive set of stakeholders.

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The dependence and the influence of important social institutions on research is central,

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and it allows us to provide get rid of the asymmetry so that we can frame the harms of unwarranted diversity of health practises.

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As salient as the risks that are carried out in research where we can see one of the fundamental

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goals of research is to address unwarranted diversity as a kind of uncertainty that we

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want to eliminate in order to create institutions that more effectively and efficiently and

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equity equitably advance the basic interests of the people who rely on them to function.

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OK, so thanks very much.

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And as I said, the book is free and open access from Oxford University Press, and I am really looking forward to our conversation.