

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. 0:05

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. 0:12

So for information being so, the talk is being recorded. 0:22

And so Robyn has set the cameras and mikes to muted, except thankfully, mine and Alex as well. 0:28

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. 0:39

So please continue off a bit further discussion until I call on the while it is so the 0:48

questions are not going to be recorded just so you don't need to worry about that. 0:55

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. 1:01

And then that will give me a sense of the order and I'll call on you in that order and 1:12

then you can unmute yourself and put your camera on if you want so that we can chat. 1:16

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. 1:24

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. 1:35

This afternoon in the US, Verizon, other today, wherever else you are. 1:44

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. 1:52

He's recently got a lot of attention. 2:02

I think you would describe this as a lot of attention for your paper with Jonathan Karl Kimmelman on against pandemic research exception, 2:05

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. 2:14

So it's great that he's here to talk about his new book. I'll hand it over to Alex. 2:24

Joe, thank you very much.

2:31
All right, well, thank you, Mark, for that generous introduction and for inviting me to be here and also thanks to Robin for all,

2:37
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. 4:41

So the first part is the origins of this parochialism, as I want to call it. 4:50

So I think it's really important to see that in the United States, 4:56

at least the birth of research ethics was really driven by a reaction against two things. 5:00

So first, there was a shared perception that there is an inherent dilemma at the heart of research with human participants, 5:09

and the fundamental problem was how to navigate this dilemma. 5:17

And there was a fear that an imperative to carry out research that was grounded in a social imperative would wind up justifying an abrogation of the rights and interests of individuals. 5:22

So that's what I want to try to show in this first section. 5:28

I'm trying to motivate and persuade you of this idea. 5:34

And then after I do that, we'll see some of the implications of this. 5:38

So part of what I want to say when I argue at length in the book that, you know, 5:43

the conceptual ecosystem of Orthodox research ethics is really narrow. 5:47

It treats research as a kind of private transaction between two main stakeholders, researchers and study participants. 5:52

It centres protectionism and paternalism, 5:57

so the be the moral crucible of research ethics takes place at the interface between researchers and participants. 6:05

And the main focus for research ethics in terms of an audience is usually the IRP, whose job it is to kind of paternalistic. 6:08

We manage the relationship between these two stakeholders. It primarily treats research as a kind of functional role. 6:17

That's a role like the doctor patient relationship or like the role of the doctor. 6:24

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. 6:31

And that really ignores the degree to which research is a social undertaking between a lot of different stakeholders. 6:36

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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,

the interests of the individual are invariably paramount. 9:08

So part of what McDermott is taking, you know, 9:16

in his sights here is the declaration of Helsinki that has as one of its claims that the interests of the individual, 9:21

you know, have to be and the physician's concern for the interests of the individual have to be paramount. 9:24

He says I believe that it's been most unwise to try to extend the principle of a government of laws and not of men into areas of such great ethical subtlety as clinical investigation. 9:32

So, McDermott, I give you this as a way of just trying to say there was a view before the institution sort of the 9:39

current before the creation of the current institutions rules and regulations in the United States. 9:43

There was a view that there was a social imperative to carry out research that that imperative was grounded in the great social benefits that research could create, 10:00

and it rested on a particular view of the relationship between society and the individual. 10:06

So this is another quote from McDermott. You know, it says society has rights too, 10:09

and it is preferable that the power to enforce these rights over the rights of the individual will be institutionalised. 10:14

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. 10:19

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 10:25

empowered to make that arbitrary judgement sometime in order to advance the right of society. 10:33

Now, part of the problem with the way McDermott frames the issue and and sort of in a certain sense, 10:43

one of the refreshing things about McDermott is that unlike other famous researchers of the day, 10:51

he says the quiet part out loud when a lot of other people are content to kind of beat around the bush. 10:58

But you know, McDermott's comments really echo arguments that we saw at the Nuremberg trial. 11:05

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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. 13:39

If you're if you're famous, like Yo-Yo Ma or something like that. 13:46

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. 13:50

In order to avoid the kind of totalitarian consequences that Jonah saw in the position that McDermott was articulating. 14:01

As he wants to demote research from an activity that serves the social, 14:13

the interests of society to an activity that serves the interests of individuals, and that becomes a kind of private, optional undertaking. 14:20

So what you see here now, so what does this piece I keep coming back to? 14:29

So some of you will know this is the front piece two halves as Leviathan. So this is the state, right? 14:33

And in what looks like it's chainmail is actually a little tiny images of individuals who comprise the state. 14:38

So we have two very different views. 14:47

We have the same conception of the relationship between the individual and the state, between individual and the collective. 14:50

But we have two different conceptions now of the relative interests at stake. 14:57

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 15:02

were in order to produce medical progress through research with human participants. 15:11

On the other side, you have Jonas who says, you know, cancer if cancer, heart disease and other organic non-contagious ills, 15:17

especially those tending to strike the old more than the villain, 15:25

continue to exact their toll at the normal rate of incidents, including the toll of private anguish and misery. 15:28

Society can go on flourishing in every way, 15:34

so society has no no concern about the the normal rate of disease that sort of pluck off individuals here and there. 15:36

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. 15:44

Interestingly, on this position now, if you have a pandemic like we're in now with COVID, 15:56

then it can be the case that if proper functioning of society is endangered, 16:05

then both of these views would line up right then I think then in his article, 16:12

Jonas talked about how it might be the case, then that its emergency powers society can take steps to preserve itself, 16:17

that that fall much more closely into the line that McDermott is running. 16:26

And I suggest later, I think that is also part of a problem here. 16:31

So the onus is paper comes out in 1969, during this time in the United States, the Tuskegee syphilis study is happening. 16:37

This the United States public health study of 400 black men with syphilis, the 200 controls in Alabama. 16:45

It involves deception, denial of treatment. No measures are deployed to stop the spread of a communicable disease that the public 16:52

health service has a social obligation to know to stop the spread and to control. 16:59

In 1969, as a blue ribbon panel that is convened to review the study and with but with all but one dissent votes 17:06

unanimously to continue the study until it breaks into the headlines and and the popular press grab hold of it. 17:14

And the scandal leads to the creation of the National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research, 17:22

and the National Commission is what creates the common rule and the whole set of institutions 17:29

and guidelines and rules that we that that constitute Orthodox research ethics today. 17:35

Actually, the National Commission produced the Belmont report that we'll talk about in a little bit. 17:40

The historical point here is relevant because it shifts the balance almost entirely in favour of Jones's position. 17:46

And a hand in glove now, the work of the National Commission, there's a kind of administrative convenience, 17:57

we want to try to make some rules that would prevent this kind of systematic abuse is as simple and easily as we can. 18:03

And so Jones's philosophical position gives the conceptual philosophical cover 18:13

for this position that's motivated by administrative convenience to some degree. 18:19

So without a social imperative, research is sort of treated now as a kind of optional undertaking. 18:24

And so everything gets focussed on what I call the IRG triangle now. 18:32

So our rulemaking talks about researchers, 18:36

the relationships to participants and how the IRB is going to insert itself in this 18:40

relationship in order to protect participants from abuse at the hands of researchers. 18:45

So this is where you get now in this in this administrative convenience, 18:53

you get research treated as a functional role because we need to know when are 18:58

individuals functioning as physicians and when are they functioning as researchers? 19:02

So we know which set of moral requirements should govern their conduct. 19:06

So, so the, you know, 19:11

the Belmont report and subsequent rulemaking annunciate criteria to distinguish when an 19:14

individual is occupying one social role rather than another. 19:14

So we talk about, you know, is your purpose to fulfil your fiduciary duty to the patient who's in 19:24

front of you? 19:24

Or are you trying to gather generalisable data? What are the means that you're using? 19:30

Are you using established effective means to benefit your patient? 19:36

Are you deploying novel interventions under conditions such as randomisation that are designed 19:39

to evaluate efficacy? 19:39

And then what kind of discretion do you have if you're in this fiduciary role where you're 19:47

providing treatment? 19:47

You have broad latitude to use your professional judgement to advance the interests of the 19:54

patient in front of you. 19:54

But if you're if you're in this information generating role, then you're required to secure a 20:01

prospective research review. 20:01

So part of what this does, though, this this framing of the ethical issues as living within the R.B. Triangle, 20:11

it eviscerates any role for the for the value of justice. 20:19

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. 20:26

Is one of the key values in the Belmont report. 20:36

But it's the least well developed and in the conceptual ecosystem of Orthodox research ethics, justice really has no distinctive role to play. 20:39

If you're if you have the background assumption and we're talking about private parties in a way that's 20:52

tacitly disconnected from larger social purposes and from other social institutions other than the IRP, 20:59

then there's not really much work for justice to do. I'd say well. 21:09

It went the wrong direction. 21:19

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. 21:20

You know, so within Belmont, beneficence are justice over the same domain and a certain sense of the bottom line. 21:29

They do effectively the same thing. 21:38

When justice is introduced, we're told Will this is about who ought to receive the benefits of research and bear its burdens. 21:41

And beneficence is ultimately about the distribution of benefits and burdens in research across different individuals. 21:48

That's why it's possible when we're talking about risk benefit, 21:56

that the risks to some individuals can be outweighed by the possibility of benefits that will accrue to other individuals. 22:00

So both of these values are treated as operating over the distribution of benefits and burdens to different individuals. 22:07

Justice, we're told, equals ought to be treated equally. 22:15

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.

24:22
They're more likely to have more precarious health and welfare on a general level.

24:29
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. 24:45

And then it's far less likely you're far less likely to secure consent from marginalised groups 24:48

for that kind of research in the absence of force fraud or insufficiently informed consent. 24:57

So, you know, all of the things that could be seen as being wrong with disproportionate, 25:04

disproportionately recruiting vulnerable populations can be explained by beneficence and autonomy. 25:13

And it's not really clear what the substance of justice is in Belmont that would provide an alternative explanation. 25:19

We really see the absence of justice then as time goes by, and in the 1990s, you know, 25:28

late '90s and then the subsequent decades when controversies in international research come to the fore. 25:34

So there are three requirements that get articulated as governing international research that there should be an adequate standard of care, 25:43

that that research should be responsiveness to host community health needs and priorities, 25:51

and that there's a duty to provide post-trial access in documents like the C OMS guidelines. 25:55

These these requirements are grounded in the value of justice, but without a substantive account of justice in these space. 26:00

A number of commentators argue that these values seem are these requirements seem arbitrary and unjustified at best. 26:09

And then Alan Wertheimer, in some recent work, has a trenchant argument where he says they're also Pereda inferior. 26:18

They raise the cost of conducting research in low and middle income country populations 26:26

that might benefit from research that doesn't satisfy one or more of these conditions, 26:30

but not conducting research there doesn't make anybody better off. 26:36

So by protecting people, Wertheimer argues, we could be making them worse off just by denying them opportunities to advance some of their interests. 26:40

Even though the research in which they're participating might be relevant to other communities 26:51

where they might get sort of the direct benefits of participation rather than post-trial access, 26:56

and where the standard of care they receive might be much lower than it would be in other places. 27:02

And so I think part of the controversy then that's happened about the norms that ought to govern international 27:10

research is the is a result of the vacuum that was created by grounding these requirements on justice, 27:16

but without having an actual substantive account of justice to do the work that's required. 27:24

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. 27:31

And you really see this with COVID. COVID illustrates this an asymmetric concern. 27:40

The risks that participants might be exposed to in research. 27:46

But then the sort of, you know, there's not an offsetting concern for the widespread tolerance for the use of validated interventions 27:51

out of beneficent intent where that doesn't necessarily translate into beneficial outcomes. 28:04

You know, 28:10

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. 28:10

You know, you see ivermectin here, you see chloroquine and hydroxychloroquine. 28:19

The beginning of the pandemic, Dieter Root, who ran one of the first quite poorly designed studies of hydroxychloroquine. 28:25

In an interview, he says, I'm not going to tell somebody, Listen, today's not your lucky day, 28:34

you're going to be getting the placebo, you're going to be dying, he told the reporter. 28:38

Root said he believes it's unnecessary and unethical. The randomised controlled trials are RCTs of treatments for a deadly infectious disease. 28:44

So what you see here is it's, you know, Root saying, basically it would be unethical for me to deny people hydroxychloroquine. 28:53

But of course, you have other clinicians who think it would be unethical of them to provide 29:00

hydroxychloroquine to patients since its efficacy hasn't been invalidated. 29:04

So you have a social status, the right state of affairs in which some people are getting. 29:09

Some clinicians are providing this intervention. Other clinicians are not providing this intervention, 29:14

but a bunch of people think that that the risks that we would be exposing people to in research 29:19

if we randomise them to those interventions are somehow worse than the default state of affairs, 29:26

of just giving those interventions directly to people without generating the information where we know whether they're efficacious are not. 29:31

You have other instances, you know, so people in the United States know when they ran ads, 29:40

some of the this is the product consortium that was looking at convalescent plasma and in their advertisements, 29:46

they say if you survived COVID 19, then you're the heroes that we need. 29:53

The plasma that's in your blood can literally save lives. 29:57

But we have to act fast, so please donate. So, you know, here are the assertion. 30:01

Basically, I mean, if you go further down on this web page, I took this from, they would say, we all, you know, 30:05

we want you to donate so that we can run some of the studies that might be necessary to evaluate, 30:10

you know, the clinical merits of convalescent plasma. But they're basically telling you in the advertisements, Hey, this can literally save lives. 30:16

Well, if it can, if we already know that, why would we need to run trials and if we need to run trials, 30:24

why are we telling people that this will save your life? And the results, of course, right, are really not very rosy. 30:28

Clinicians used hydroxychloroquine with therapeutic intent on a large scale, but the recovery trial showed that amongst patients with COVID 19, 30:37

those who received hydroxychloroquine didn't have a lower incidence of death at 28 days than those who received usual care. 30:48

They did have a longer hospital duration. And then there were some populations that were more likely to progress to the 30:56

outcomes of mechanical ventilation or death than people in the usual care group. 31:03

Yet things that weren't quite as bad with convalescent plasma in the United States, 31:09

100000 people received convalescent plasma outside the context of a clinical trial. 31:13

But again, recovery says there was no significant difference between convalescent plasma and the usual care group. 31:19

So it didn't seem like it was harmful, but it certainly absorbed the time, energy and resources of a wide range of people. 31:27

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, 31:35

relegating it to a kind of private activity now that that gets evaluated within the narrow confines of the IRP triangle. 31:50

Results in this ecosystem that has all these problems, you have a narrow set of stakeholders with a narrow focus on one point, right? 32:00

I IRB review is one point in a much larger process where many more stakeholders 32:10

have already made decisions about what the protocol is going to look like, 32:15

what the study is going in, what what questions are going to be asked and answered. 32:19

There's the invisibility. The knowledge that research produces and its relationship to a bunch of social 32:24

systems are basically invisible within this within this cognitive ecosystem, 32:30

other than the idea that there needs to be social value to research a concept that up until very recently was not, well explicated. 32:37

Social institutions are invisible, even though research calls them into action and and the information that it 32:45

generates is supposed to feed back into them and their ability to function. 32:53

There's a keen awareness of risks inside research, 32:58

but a far greater tolerance for unfound practise on a large scale outside of research and no social imperative 33:01

to close knowledge gaps between the health priorities of a community and the ability of the communities, 33:09

its social or health care institutions to meet those needs or to rectify inequalities in the 33:16

ability of those systems to address the health needs of the diverse populations that they serve. 33:22

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.
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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.
35:25

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. 35:32

In other words, the basic institutions of society have to function to secure for each person their basic interest in being able to formulate, 35:44

pursue and revise a life plan. And so basic interests now can be threatened by a wider range of things. 35:52

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. 36:11

So for our purposes, I'll stick to sickness, injury and disease. 36:16

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 36:20

focus of what a just society is supposed to help secure for individuals is what grounds 36:29

now a notion of justice that takes research away out of the sphere of a private activity 36:35

and puts it in the sphere of social activity that produces a unique public good. 36:43

So this is a unique public good because research with humans is often the only way to generate the information that we need to 36:48

bridge gaps between the ability of individuals to function in this basic way and the capacity of health related social systems, 36:57

public health, individual health live close to client health system to function in ways that will 37:06

safeguard and support and advance those those abilities of individuals effectively, 37:12

efficiently but also equitably. So in order to be able to do that in order for health systems to be able to effectively, 37:19

efficiently and equitably advance the basic interests of people in those communities, we have to understand the aetiology of disease. 37:27

We have to understand the disease mechanisms so that we can intervene on it to try to prevent the spread, 37:34

to try to manage this disease spread or progression of disease, 37:41

or provide treatment to patients to either cure them or mitigate morbidity and mortality. 37:45

So this is the the the first part of the social imperative that social institutions
37:55
of a just state have to secure the life and liberty and welfare of their members.
38:02
The feeling that function in the face of uncertainty requires the knowledge necessary to
safeguard health and to make equitable,
38:06
efficient and effective use of the wide range of social resources that go into creating the social
systems that fulfil this function.
38:15
And so, you know, a central claim of the book is that there's an imperative to conduct research
that closes these
38:25
knowledge gaps that will enable health systems to secure the basic interests of community
members.
38:31
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.
38:37
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,
38:50
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.
39:13
Basic institutions of society must function to secure the common good, i.e. each person's basic
interests.
39:20
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.
39:31
So research is an activity that gets extended across time. It involves multiple stakeholders.
39:38
It calls into action various social institutions, whether they're funding institutions, regulatory
institutions, health care, providing institutions.
39:44
And it also generates the information it feeds back into those institutions and shapes their ability
to function.
39:53
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,
40:09

as a scheme of social cooperation that must be organised on terms that respect the status of individuals 40:16

as free and equal means that there's also an imperative to sure to ensure that it's a voluntary 40:23

undertaking undertaken with free and informed consent in the same way that society requires the 40:30

widespread participation of people who occupy many different social roles like voluntary firefighters, 40:36

paramedics and other people. 40:44

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. 40:46

Part of the way that we secure the credible assurance those people that they won't be 40:59

an arbitrary decision made against them in order to advance the common good to use. 41:04

McDermott's phrase is you have prospective review to eliminate unnecessary risk to ensure an appropriate baseline 41:08

of care is provided within medical research and also have provisions that prohibit domination and abuse. 41:16

So, so this point I was making free societies require many social functions to fill in the important social obligations, right? 41:24

We need teachers. We can't get rid of ignorance. We can't combat ignorance without teachers. 41:32

We need physicians. We need researchers, 41:37

many volunteer firefighters and paramedics in all these people that provide important social services on which our health and welfare depend. 41:39

And then what we do is we try to shape those social institutions so that individuals can see that social role as an avenue 41:47

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. 42:27

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? 42:43

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, 42:52

there's for a framework for evaluating risk that satisfies a bunch of really stringent ethical principles that can ensure social value, 42:55

equal concern for individuals, equal concern for the welfare of people inside and outside of these trials, 43:03

and a prohibition against impermissible gambles where basically impermissible gambles are the sort of thing where you say, 43:09

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. 43:20

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. 43:36

So if you think about international research as an example, now, 43:43

these common requirements from the OMS guidelines that really didn't have a clear normative foundation now have a much more solid foundation. 43:47

The responsiveness requirement is itself a direct requirement of justice. 43:57

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 44:10

health needs of the people who live in those communities because they have a fundamental moral claim on the basic institutions 44:18

of their society that they should work to advance their fundamental interests in being able to pursue a reasonable life plan. 44:24

The requirement to provide an adequate standard of care. Larry, to respect participants is free and equal. 44:33

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. 44:47

And the requirement for post-trial access is just an implication that if you generate new knowledge, 44:56

it's not going to safeguard the health of anyone unless it is integrated into the social systems that have, 45:02

as their social function, safeguarding the health and welfare of people. 45:09

Another implication of this view is that the IRIB triangle and the traditional view that, 45:16

like people, scholars in research ethics are primarily speaking to researchers or IRB members. 45:21

We have to we have to broaden the set of stakeholders that we are talking to because we have to broaden that are 45:28

the realisation that many different stakeholders make decisions upstream of IRB review and downstream of study, 45:36

study, conduct and study completion that affect responsiveness and and the availability 45:46

of the knowledge and the interventions that are developed within research. 45:53

So funders and sponsors, crowds 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. 46:08

Patent protection. IP protection that incentivise private and public actors to invest their time, 46:17

energy and resources in determining which questions and where they put their time, energy and resources. 46:25

So lawmakers and policymakers have to be some sort of a fundamental interlocutor for research 46:33

ethics when it comes to thinking about what the priority research questions ought to be. 46:40

Journal editors and professional societies, health systems, clinicians,

patients and future researchers may be part of the reason for ensuring the quality of scientific
46:45
research is not about the risks that poor quality research might impose on study participants.
46:51
That's sort of how you have to funnel and frame issues about scientific quality in the sort of the
46:58
current research ethics ecosystem.
47:05
But, you know, research the information that studies produce is consumed by a wide range of
stakeholders,
47:16
health systems, clinicians and future researchers.
47:23
And so they rely on that the quality of that evidence in order to fulfil social obligations that they
have.
47:26
So we have to move also away from a protectionist view where the primary function
47:35
of research ethics is protectionism to one where the idea is the primary
47:41
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,
47:46
parochial interests at the expense of the common good. So a lot of stakeholders in in in research
engage partly to advance parochial interests.
47:56
Profit promotion, access to novel treatments. The prestige of being a research institution.
48:06
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.
48:14
Framing the IRP review in protectionist terms,
48:25
disconnects it from some of its actual important functions where it really does work to ensure
that the cooperation amongst these
48:28
different stakeholders is aligned with producing higher quality research as well as protecting
the interests of study participants.
48:36
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.
48:47
The study design A lot of these questions now pose these questions beyond the confines of the
single protocol to the IRP.
48:57
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,
49:13

but whole sets of study protocols. 49:19

Well, those things become very salient in this wider formulation precisely because they implicate the efficiency with we. 49:21

Research uses scarce resources, including how many people are required in order to answer a question. 49:29

The bandwidth of information that research produces about a question whether that which stakeholder is that information is really useful for. 49:37

And then finally, as I said, law and policymakers need to be a fundamental focus, 49:46

both in terms of how they set domestic research priorities and how we engage in our research, our collaborative research abroad. 49:53

And I think vaccine equity and the fundamental problems that we're having right now 50:04

around vaccine equity sort of shine a light on how this whole ecosystem of we had to. 50:10

We had to answer a novel question. We generated now a new resource. 50:16

And now we've got to carry out the difficult work of equity of making that resource available to all 50:21

of the communities that require it in order to secure the basic interests of their community members. 50:26

So in conclusion, I are you in the critical part of the book that the boundaries of research ethics are arbitrarily narrow. 50:33

A bunch of current requirements seem arbitrary and self-defeating. 50:41

There are a whole raft of stakeholders who exert concrete and real influence on the way research is done, 50:46

but who are basically invisible and whose conduct is invisible within Orthodox research ethics and the relationship of research 50:53

to important social institutions and the moral responsibility of those institutions is far less visible than it ought to be. 51:00

In place of this, I offer a much broader conception of research as a social activity spread across time involving multiple stakeholders. 51:09

It's one element within a much larger division of social labour in this position. 51:18

Issues of justice becomes central. 51:22

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

51:25

The full range of ethical issues now that are salient to the conduct of research can be framed while considering the duties of a much more comprehensive set of stakeholders.

51:33

The dependence and the influence of important social institutions on research is central, and it allows us to provide get rid of the asymmetry so that we can frame the harms of unwarranted diversity of health practises.

51:38

51:43

51:50

As salient as the risks that are carried out in research where we can see one of the fundamental goals of research is to address unwarranted diversity as a kind of uncertainty that we

52:01

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

52:07

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

52:13

52:19

OK, so thanks very much.

52:27

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