



Presidential Commission  
*for the Study of Bioethical Issues*

TRANSCRIPT

Implementing Federal Standards - Ethics Issues

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**DR. WAGNER:**

For session 4, our Chair.

**DR. GUTMANN:**

If Ron Bayer and Joseph Fins would come on up, thank you. We're continuing the issue of implementing Federal standards and moving to two people who are experts on the ethics on this topic. We'll begin with Ron Bayer, who is a Professor of Sociomedical Sciences and co-director of the program in the History of Medicine and Public Health in the Mailman School of Public Health at Columbia University. Dr. Bayer's ethics and public policy research has had a special focus on AIDS, tuberculosis, illicit drugs and tobacco. He is also Senior Advisor to the HIV Center for Clinical and Behavioral Studies at the New York State Psychiatric Institute at Columbia University and a consultant to the World Health Organization. He is an elected member of the Institute of Medicine. Welcome, Ron.

**DR. BAYER:**

I was warned that Amy is a very severe time keeper and since I don't like to talk very fast I decided to restrict myself to three issues related to the implementation of the ethics of research within universities and specifically within departments and schools that focus on the social sciences. I want to start with a brief vignette. Several years ago the question arose about whether or not oral history ought to be subject to IRB review. Oral history is a central way of conducting understandings of the experiences of people. And the remarkable part of that debate was that oral historians lined up and argued that what they did was not research, and didn't fall within the definition of research, so that they could avoid IRB review. And in fact someone responded by saying, in fact, it wasn't research because it didn't produce generalizable knowledge.

I mention that because my main concern today is to raise issues about how what began as a venture in confronting abuse -- the misuse and abuse of research subjects -- has become something very different. And that is a beaurocratized system of regulation that often misses the core of what the mission had began to do, and that actually has turned itself into an object of ridicule and sometimes contempt in a way that I think is dangerous to those who believe in the ethical conduct of research.

I, in preparation for today's meeting, I actually read the article that was written by Bob Levine and Norm Fost that you circulated. And I was struck by that. I mean, Bob Levine is known to be contrary and has often raised questions about the shape of the regulation of research in the United States. But there was something very powerful in what he had to say, I think. And that is that he argued that the system of regulation -- and all systems of regulation in some way, to the extent that they are

systems, have to be bureaucratic -- has begun to assume features that contradict the mission that this institution was supposed to achieve. I can only speak about what I see and hear around me, and this is a matter that I think the Commission might want to undertake some empirical work about. There's a difference between evidence and a story, and there's a difference between belly aching and kvetching and having a legitimate concern. So again what I have to say I think should be the beginning of a process of research of investigation, not the end. I listen to people talk about going to the IRB and they talk about it in the way one would talk about appearing before a co-op board or having an audit at the IRS.

**DR. GUTMANN:**

That is an inside New York joke, you realize. We don't have co-op boards in Philadelphia. Not as many, at least. (Laughter)

**DR. BAYER:**

The co-op boards, in case you don't know, investigate every aspect of your life to see whether you are good enough to be a neighbor. So I listen to this and I listen with concern because what should be a process of enhancing both the quality of the research and the ethical attention that researchers ought to pay to research subjects and the consequences of research has become something very different. And I say this as someone who is not opposed to regulation. I see regulation as central to a Democratic society. If it's transparent, if it's efficient, etcetera. And I hear this concern in an institution where people by and large are committed to human rights. That is, it is one aspect of the culture of schools of public health that the attention to vulnerable populations is high. And concern about the mission of public health being the mission to protect vulnerable populations is central.

And so when I listen to this and I listen to people saying: Oh, the Goddamn IRB, forgive me, and the picayune questions they raise, and the impediments they impose upon the ability to do this work. I listen and I'm concerned and I think it is something that ought to be a matter of concern to all of us. That is, has the structure we have created become something very different from what we wanted and how do we fix it?

And that is central fundamental question, not a matter of tinkering. The second issue I wanted to mention, and it's related to this, is the way in which we assure that people who are going to conduct research are familiar with basic principles, understand the concepts, understand the tensions, etcetera. I, like everyone else at the Mailman School of Public Health have to take an online test to guarantee that I have read the right things and understand the right things. I did it several years ago and just last month I was told we now have to do it every three years, so I had to do it again. I have to tell you, it is the most insulting experience to sit in

front of a screen, to download a text and then a series of questions to which there is only one right answer, and if God forbid you think that there may be an ambiguity or an uncertainty, you get the answer wrong. What has happened, and I listen to people talk about taking these tests, and they talk about it the way Russian social scientists used to talk about having to learn the right Marxist doxology in the old Soviet Union. They have to learn something, spit it back and give the right answer, and if you don't get a good enough score, you can't do research, you have to take the test again.

How it happened that we came to think educating people about doing research in an ethical way became so contorted that it becomes like the joke about how kids used to learn the Pledge of Allegiance and they didn't know what any of the words meant, and so they garbled it up in some funny way and you would hear versions of what the Pledge of Allegiance is. It is like that when people talk about ethics of research as they -- look what you can do is you can download the text, put the question in front of you, read the text, find the answer. That's not education. And the reason I see it as a matter of concern is what it does is it raises contempt for the idea of education and becoming kind of sensitive to ethical complexities. And that's not where I think we should be going.

It is in some way analogous to what has happened to the issue of privacy and the HIPAA regulations and the incessant plethora of pieces of paper from banks and insurance companies, printed and typed, I certainly can't read anymore, that tell you about their privacy protections. What do people think? All this privacy protection stuff is junk. Because it has become utterly bureaucratized.

So, what's the challenge it seems to me to this commission? There are many big issues about what kinds of research internationally and globally in a world that is increasingly unequal is ethical, but it seems to me -- it seems to me that it is time to revisit in a fundamental way both the institutions we've created, how they function, and how we educate people about fundamental ethical issues in research.

I don't deny that there are certain fundamental things one can read and learn. One takes drivers test, one has to learn what a left hand signal is and what a right hand signal is. But there is something off when people see the entire process, not as something they feel proud about, but as something they experience as, in a way mortifyingly stupid, and stupefying -- that is what it is, stupefying.

One last point and I'll stop. And this relates in part to this. I have been interested for the last several years in the question of ethics of public health surveillance, a central piece of what public health is about. You

can't do public health without surveillance. The question of course is: what is the difference between public health surveillance, which is public health practice and is not subject to IRB review, and public health research, which is subject to IRB review?

There is entire layer of personnel at the CDC whose I think sole function is to try to distinguish between public health research and surveillance activities. And I'll tell you, I'll end with the vignette I started with a vignette. I spoke to a guy and he said: You know, I got this protocol on my desk and I had to review to decide whether it was research or not. And I reviewed it and it got lost in the mess on my desk. So they sent it to me again. And I reviewed it again. And he said, then I found both and in one instance I had called it research and in one instance I called it practice. What does this mean? That he's inconsistent, that he's foolish? No. It seems to me that it's a complicated issue, we haven't resolved it. Trying to resolve it with a kind of formalistic definition of what is research seems to me inadequate to the challenge. It seems to me what this suggests and this is a huge domain in public health is the need to go beyond the issue of articulating standards for research qua research and say there are undertakings that don't fit the definition of research -- maybe oral history, maybe not surveillance or not -- and to think about what ethical standards ought to govern all those forms of inquiry, not simply those that bureaucratically fall within the niche. I'll stop there. Thank you.

**DR. GUTMANN:**

Thank you very much. Joseph Fins is the E. William Davis Jr. Professor of Medical Ethics and Chief of the Division of Medical Ethics at Weil Cornell Medical College, where he also serves as Professor of Medicine, Professor of Public Health, and Professor of Medicine in Psychiatry. He is also, if that isn't enough, an Attending Physician and the Director of Medical Ethics at the New York Presbyterian Weil Cornell Medical Center, as well as a member of the adjunct faculty at Rockefeller University, where he is a Senior Attending Physician at Rockefeller University Hospital. His current scholarly interests include ethical and policy issues in brain injury and disorders of consciousness, palliative care, research ethics in neurology and psychiatry, and methods of ethics case consultation. Dr. Fin is an elected member of the Institute of Medicine, President Elect of the American Society for Bioethics and Humanity, and he serves as a member of the Hastings Center, Board of Trustees. Welcome.

**DR. FINS:**

Thank you, Madam Chairman and Commission Members. I'm really honored to be here today as you undertake your important deliberations to see so many friends and colleagues. I very much appreciate the opportunity to speak with you and your service, as well. What I'd like to

do is to focus my remarks on research on subjects who lack decisional capacity, the Common Rule, and research that represents more than a minor increment over minimal risk without the prospect of direct medical benefit to individual subjects.

Before I begin, let me state that I'm also a member of the New York State Task Force on Life and the Law, and the Task Force is considering many of the same issues. My comments today, I've been instructed, are mine alone and do not represent that body. And I will provide the Commission with my full text.

So my comments will be informed by my participation in investigative work involving patients with disorders of consciousness, namely the vegetative and minimally conscious states. I served as one of the 4 lead investigators on the 2007 Nature study of the first use of DBS in the minimally conscious state, and in my role as a physician-ethicist, helped to design the ethical framework for that trial. I've also been involved with neuroimaging studies seeking to understand the ethical implications about emerging knowledge about the biological sub-strata of these conditions, mechanism of recovery and efforts to improve diagnosis and prognosis, and ultimately develop treatments. I'm also currently completing a book on neuroethics and disorders of consciousness to be published by Cambridge University Press, which is based on my participation in this work, as well as in-depth interviews with family members of patients with disorders of conscious, for which I obtained IRB approval.

Because brain states like the vegetative state and minimally conscious states can be confused, either through errors of omission or commission as during the Schiavo debate, let me seek to lay out a few key definitions while I speak about them. The vegetative state, first coined as a syndrome without a name by the Scottish neurosurgeon, Brian Janet and my late teacher, Fred Plum, in 1972 as a state of wakeful unresponsiveness, an eyes-open state in which there are sleep-wake cycles, but no response to the environment, say for those that are reflexive. Biologically this state has been understood as a functional brain stem in the absence of higher cortical function, although recent neuroimaging studies have brought this definition into some question. Prominent cases like Quinlan, Cruzan, and Schiavo have all featured patients who are permanently vegetative.

The diagnostic criteria for MCS are called the Aspen Criteria. They were first published in Neurology in 2002, and they have allowed, and indeed they promoted, diagnostic refinement between these two brain states. The minimally conscious state, in contrast to patients who are vegetative, are conscious, albeit minimally so. These patients respond to their environment. They may show intention, attention, memory. They may

grasp for a ball, they may say an occasional word, they may track when somebody walks into a room. But these behaviors unfortunately are episodic, they don't happen all the time. Typically a family member sees behavior and ask a staff member to come in to re-demonstrate the behavior and it doesn't happen and the family is written off as sort of having wishful thinking. But in fact, it is the biology of the state that causes this confusion.

Indeed, a recent study has revealed that 41% of vegetative patients in long term care facilities were in fact minimally conscious when properly assessed using a validated neurobehavioral instrument. We know of the locked-in syndrome, but this is, one person has said, the locked-out syndrome. Just imagine being conscious at some level and having everybody think you were permanently vegetative when you weren't. You know, 41% is an error rate that would be unconscionable in any other area of medicine and reflects the marginalization of this population that has suffered from what I have described as a societal neglect syndrome, invoking the neurological analogy of patients with parietal lobe lesions who neglect part of their visual field. These patients have been out of our societal gaze and mis-plemics and notions of futility that lead to the mistaken belief that nothing can or should be done to ameliorate their condition.

But they make a justice claim on our health care system, as conscious individuals who have been labeled as permanently unconscious left to linger in their nursing home beds. They make the justice claim in our neuroscience community to be able to partake in the benefits of new technologies which might restore or augment their abilities. And finally, for us, they make a justice claim on us bioethicists and the bioethics community to figure out novel ethical and regulatory constructs that would allow surrogates to authorize their participation that could make a difference in their lives.

There is a sound scientific predicate for this argument. Biologically, the minimally conscious state patient is different from the vegetative patient in the sense that their brains are functionally integrated and that integration is the biological context, which is central to questions of ethics and justice. Brains which are or have the capacity for functional integration are amenable to interventions that might harness this latent capacity and restore functional communication and an ability to interact with others.

This was the case with our work with DBS and minimally conscious state, which I would like to briefly describe. In the Nature paper, we described 38 year old man who had been in a minimally conscious state for 6 years following an assault. He had an initial Glasgow Coma Scale of 3, which is as low as it can go without one being dead. He had been

vegetative for 3 months before becoming minimally conscious. All he could do was simple command-following and sometimes visual pursuit. He had no incremental improvement for years. But with the results of the 6 month double blind cross over study, he showed an increased level of arousal. First time he was able to eat by mouth, previously he had required a PEG tube. And he had regained ability to communicate, up to 6 or 7 word sentences. He could say the first 16 words of the Pledge of Allegiance, not knowing initially what it meant, and tell his mother that he loved her. Additional details of this are in papers that I provided.

Now it is well appreciated here that subjects who cannot provide autonomous consent constitute a vulnerable population, open to exploitation, unable as they are to protect their interests or defend themselves against unwanted and unconsented to interventions. This inability to provide consent for research participation may either displace authorization to surrogates or lead to a protectionist ethics that excludes this population from research writ large. Or it can lead to distortions or confusion, and what is meant by the prospect of direct benefit and confusion about early phase research itself, which is primarily concerned about safety and not efficacy.

Now it's important to bring these issues about consent forward at this time because of the recent news of the unethical behavior of the US Public Health Service activities in Guatemala decades ago. And that reminds us of the impetus for the original National Commission charged in Congress under the National Research Act of 1974 just after the revelations of the Tuskegee syphilis study. The National Commission, given its historic moment, made human subjects' protections its primary focus.

As outlined in the Belmont Report and elsewhere, your predecessor Commissioners stressed three principles: the centrality of respect for persons, beneficence, and justice, and the associated applications of these principles in the process of informed consent, risk-benefit assessment, and selection of subjects. But given the shocking revelations of Tuskegee, the National Commission appropriately focused on human subject protections, not the promotion of access to research. When it came time to consider the question of justice, the emphasis was that the burden imposed by research be fairly distributed around society and not that access be increased. Vulnerable populations should not shoulder a disproportionate share of the load simply because they were available for research, and given the legacy of cases like the Jewish Chronic Disease Hospital and Willowbrook here in New York, when and if research were to be conducted in vulnerable subject populations, appropriate justification would need to be presented to IRBs before approval could be made.

Having said this, it is also important to know, and I urge you folks to look at this, that the National Commission also wrote a congressionally mandated report on psychosurgery a year before the Belmont Report was released, in which they did actually outline a mechanism for surrogate consent in research and practice. These regulations, however, were never put into practice.

Restrictions on research for vulnerable subjects including those with decisional incapacity were further enumerated in the Common Rule and the closest we get to a standard for research without the direct prospect of benefit is in the more liberal category of 46.406 in the children's section of the Common Rule, which asserts most notably that research is possible under conditions in category (C) where the intervention or procedure is likely to yield generalizable knowledge about the subject's disorder or condition which is of vital importance for the understanding or amelioration for the subject's disorder or condition. To address these issues the Clinton era bioethics commission relied upon regulatory restrictions between research that was efficacious versus that which was not.

But in the interest of time, what I'd like to do is move to my conclusion and say clearly, the conduct of research without consent over the objections of a competent individual is an ethical lapse without justification. But this does not translate into making research authorized by surrogate suspect. This is paternalistic and robs a surrogate of an important decision-making role.

Through my IRB-sanctioned interviews with families with loved ones with disorders of consciousness, I have come to appreciate the burdens they have assumed and strongly believe that with this assumption of responsibility, should come additional authority to consent to research with appropriate IRB oversight. Nor should research without autonomous consent be problematic when the object of the intervention, as it was in the case of our work with DBS and MCC -- the object of our work was the restoration of functional communication and the restoration of some degree of personal agency. This was indeed what happened in our study. Although the subject was mute prior to implantation, when the stimulator was in place he was able then to voice preferences, and at the level of the dissent. When asked if he wanted to continue with his therapy one day, he said no and that was actually a restoration of his ability to participate in decisions that mattered to him. So what I would like to do is to conclude with this justice claim for this population. Indeed, meet the civil rights -- think about it, the civil rights of those patients who are conscious, but need time and a scanner or need a \$50,000 device. Again, I don't want to promote a therapeutic misconception because that is yet to be vetted, it's still phase 1. But

assuming the technology moves forward as it always has, we're going to have a challenge for this population to provide them with resources. What I'd like to do is make 6 recommendations to facilitate surrogate consent.

One, despite the recent historical revelations about Guatemala, avoid the temptation to respond with additional prohibitions on appropriate and sound surrogate research. Do not respond to these egregious and horrifying findings by further excluding a population in need of research participation. Two, create a fourth category for the Common Rule for research that involves more than a minor increment over minimal risk without the prospect of direct medical benefit, and stipulate the conditions when surrogate consent might be permissible. Three, appreciate that the Belmont Report's commentary about equitable distribution of the burdens of research could equally be argued suggesting fair distribution of benefits. Four, avoid the temptation to create a super IRB as originally posed by Jay Katz and the Psychosurgery Report in 1977 to tackle the difficult cases. This will prove, I think, unworkable and displaces problems better solved locally with sufficiently skilled IRBs. Five, endorse a mechanism for prospective authorization of research advance directives, but do not rely upon this approach at the exclusion of empowering legally authorized representatives, and that should happen unequivocally in Federal law to recognize the authorization, the status of the legally authorized representative to consent to such research. And this can be facilitated with a number of models. And finally, make a recommendation to the President and Congress for additional or, in this budget strapped period of time, reallocation of resources to support research compliance and research ethics programs in intramural and extramural programs necessary to support these recommendations. Thank you for the privilege of being here.

**DR. GUTMANN:**

Thank you very, very much. We now have time for questions. I'm going to recognize Christine twice was cut off right before her question.

**DR. GRADY:**

My questions are for the last panel. I'll ask these guys. Thank you very much. Thank you both very much for -- Okay. I'll talk out of this one -- for your presentations. One of the themes that we've had throughout the day is an issue of, among others, the distinction between compliance and ethics. And I think Ron, you spoke very eloquently to the system as it's been -- the system that's become from good faith efforts in the beginning, has become one of a burden and a hindrance to good ethics in some respects. And earlier some of the panels talked about the importance of not just focusing on compliance. But we heard just before you from the FDA and the OHRP. And so I found myself thinking when

they were talking, where do we make that split? It seems like OHRP and FDA might have to stick with assuring compliance. They may not be able to do much beyond that, maybe publicize Best Practices or something like that. But I heard you talking about a more fundamental revision of the whole mission, what are we trying to do here and starting from the ground up.

And then I want to build in your recommendations into this question in the following sense. One of the things you said, Joe, was to add more regulations or at least address the issue of people who can't consent for themselves and maybe add another risk category and things like that. That debate, as you know, has been going on for a long time and the question I think that many people feel is part of that debate is, is it good to have more regulations or is it better to allow the decisionmakers, the funders, the sponsors, the investigators, and IRBs to take each instance of research with people who can't consent and decide whether it is okay on its own. So they're connected in that regard.

**DR. BAYER:**

In another context, I had an opportunity recently to reread some Max Weber, who I haven't read in about 40 years. And he talked about the iron cage of bureaucracy and in some way, I think people who have the responsibility to enforce rules and regulations have a very heavy burden, they have a burden to do it right and they work under huge pressures. I don't think they are malevolent, but it seems to me this process needs something in addition, so that the process of regulation and compliance is not the same as educating people to be aware of the ethical complexity of research. And monitoring what we do in our education to make sure that in fact we are getting there.

I took the charge of coming before you today as a serious one. I'm not an expert on research ethics, but I am a pretty good listener, and I do my own research and I know when I think that this is picky, the requirement is picayune and bureaucratic, and when it really reflects – you know, people used to say: the consent is not the consent form. So that's the message, that there is something more. And I think what's happened is that process of ethics review and ethics education has become like a form. And we're not thinking sufficiently about what the process of doing ethical research is. Again, it's an observation, I may be completely wrong. It requires, it seems to me, a systematic investigation of how people experience the process of undergoing and whether people really know something more now than they did 10 years ago.

**DR. FINS:**

Okay. So it's a perfect question and I want to align myself with what Ron said, but I think we need that fourth category to overcome the preexisting regulations, because they've created a box that is very hard to

get out of. And we've actually written papers about recommending an ethics consultation service in lieu of, or in addition to the IRB, which is meant to be adversarial, and not necessarily collaborative and collegial. And so we've actually done some experimentation with moving the process upstream. In fact, what my role was on that project was to be an ethics consultant and to figure out a way to do precisely what you suggested to make the ethical arguments, the robust arguments in scholarship. We turned this project into not only a DBS study, but an ethics experiment of ways to articulate it.

So I think that one of the things we really need to do is to move, is to overcome the confusion between a regulatory stance and an ethical stance and I think good ethics is when to say no, but also ways to figure out new ways of saying yes if you are making a different claim. And I think that nonmalevolence, the notion of not doing harm, I think is historically the predicate because of all the horrible things that happened Nuremberg, Tuskegee and the recent revelations, we've actually kind of seen the safest research that which never occurs. But that would lead to a kind of stasis that none of us would find acceptable. So I think we're going to have to create a little new bureaucracy to undo the bureaucracy that we have in a way that allows for more thoughtful work to occur. So I agree with you long term, but I think there is strategic and tactical response to the question.

**DR. GUTMANN:**

Nita.

**DR. FARAHANY:**

Great. Thank you. These were both very interesting and built well on what we already heard today. I want to build a little bit on Christine's question because I've been hearing the repeated sentiment that IRBs have run amuck and that they have done so because they are at odds with what the original intent of the Common Rule was, that they are expanding well beyond what is required by Federal regulations to have compliance, and that they are often doing that with concern to protect their own institutions rather than necessarily to protect individual research subjects, and so the ethics and the protection of individual research subjects is being lost in the process. But if a lot of that is happening at the institutional level, expanding well beyond what is required with motivations that are designed to protect the institution itself rather than to protect individual research subjects, I'm wondering how much at the Federal level it's going to matter in restructuring and rethinking regulations, except somehow creating a process whereby there isn't an incentive to have to protect themselves. But if the protection is coming from areas like concerns about tort suits or other types of suits rather than from compliance with Federal regulations, then I'm not sure how much restructuring at the Federal level is going to be

affected. So I was hoping you can speak to that because I took your talk to also be a concern about new types of regulations that might happen really at the institutional level rather than at a Federal level suggesting there should be greater safeguards on the surrogacy type decision making happening. So this is really to both of you.

**DR. BAYER:**

One of the chilling things that probably led to this escalation were the site visits and the shutdowns of a lot of very prominent research centers that has made every IRB somewhat paranoid. I don't think it is tort issues, I think it's about losing their Federal assurance and allowing research to go forward. And so I think that was an action of the Federal government coming in and doing these investigations. So I think that is one thing that can be -- making it more collegial and less adversarial; making it constructive versus destructive. Saying this is how we should do a better job of that.

The other thing is that IRBs spin multiple times churning protocols. Sometimes we've done audits of IRBs and I'm not sure what the knowledge base is, there have been a very small number of studies looking at what IRB members actually know nationally and I think that we need to really improve their infrastructure if we're going to delegate responsibility to them. And I do think they missed the forest from the trees. The other thing, it is not in any institution's interest to have a protocol go through 3 or 4 times because they lose a revenue stream. It is all about funding if you look at it that way. I think we need to strengthen IRBs again and make sure, there should be a rule that someone who is trained in ethics, okay, sits on an IRB, because what happens is they get totally distracted by the regs and they don't see the big picture.

**DR. GUTMANN:**

Can we just underline that, it is an answer in some ways to Christine's question. It is not that compliance is incompatible with ethics, it is that people who do compliance should realize what the ethical rationale is and if it doesn't have an ethical rationale in a particular instance, should question whether there may be another interpretation of the rule. There are very few rules that don't have multiple interpretations.

**DR. BAYER:**

That is why have philosophy.

**DR. FINS:**

I just want to say something about the process of change and how, whether it happens internally or is governed by external forces. In the AIDS epidemic there were huge battles about whether or not people had a right to be research subjects, not to be protected from research, but the

right to be research subjects. And in fact some of the most interesting cases emerged when gay men said: you are protecting us -- when there was no treatment -- you are protecting us out of the only possibility of some intervention that could help us. When prisoners demanded the right to be research subjects because they weren't allowed to be research subjects and without research, I'm going to die. The change didn't take place because -- it certainly didn't take place because ethicists alone had a conversation about what needed to be done. It took place because of external pressure that demanded something more than this protectionist ethos which had twisted the purpose of protection.

**DR. GUTMANN:**

John?

**DR. ARRAS:**

First, a comment on vulnerability. Ron, you're recounting history quite correctly there. As Carol Levine put it so well, research ethics was born in scandal and raised in protectionism. You know, which gave rise to a very intense focus on protecting people from the researchers and the whole notion of vulnerable populations became a really important concept. And of course that did give rise to the backlash that you describe, right? So, first AIDS patients, then women, children's advocates, all saying that our people are dying because of lack of access to drugs and biomedical innovation. So, I just want to point out this is another one of those balancing act problems that we have because there is also a lot of talk in research ethics, especially on the international front, about protecting vulnerable populations and we often don't bring those two -- Sergio was mentioning this earlier today -- we don't bring these two conversations together, I think, the way we need to.

But Ron, I want to get back to your critique of the system. In a sense I think we are victims of our own success, right? We pushed for ethical reform of the system, real oversight, and now we're left with this beaurocratized system, really a kind of nit picking monster. I'm as stupefied as you are by these kinds of computerized lessons, all right. I am personally insulted when I have to take one of these for affirmative action training at the University of Virginia, right?

So I know exactly what these researchers are feeling, but here is the problem. We're in a situation where we want mass education of people in a kind of fine tuned ethics of research and clearly the notion of these mechanistic web lessons is not the answer. But I'm wondering what is? Clearly, we want everybody to take your seminars at Columbia University for an entire semester. So I mean that would really do the trick, I think, right? But, so that's clearly not going to happen, right? It's incredibly hard to make room in a medical school curriculum for ethics and I think that my hunch is that the medical establishment allows us these pathetic

web based tutorials, you know, in a grudging kind of way. You're taking up our valuable time, right? So the question is in between a seminar at Columbia and these web tutorials, what kinds of alternatives can we imagine?

**DR. BAYER:**

Professionally I feel a bit like a kibitzer here. But here is the -- I think it would be good to look around the world, look to Western Europe, look to Canada. Whatever. It seems to me that we're not the only nation confronting this question of how best to kind of instantiate a respect for the ethics of research. It may be, it just may be that other people have come up with an answer we might learn from. And again I don't know what they have done, and I don't know how far it's gone, but certainly in the context of Europe, in the context of Canada, Australia, we might actually see something that is different from what we're doing that might be educated.

**DR. FINS:**

One of the things we've been doing when students are doing research and they have to apply to their IRB, we help them. We say, we can assist you in the formulation of your protocol, let's explain why that informed consent document just doesn't make sense because it is written at 12th grade level or it's not culturally sensitive or something. Learning by doing, it's a old Dewian notion, that we don't add to the time, we just make it more efficient. That is one suggestion: integrate it into the doing of the work every single day.

The other thing is in response to other examples is Spain. Diego Grasi, I don't know if you know him, has a master's program in bioethics that is funded by the Federal government in Spain. And what he does is he has mid-level career docs come to Madrid for a week a month for two years, they get a master's degree in clinical and research ethics, which is kind of, they have a single Committee there, they don't have IRBs and ethics committees. And they leave with a Master's degree and then they are funded to be the IRB chief and ethics committee chair in their local regional hospital under that rubric. It's worked exceedingly well.

Spanish bioethics society has about 300 members and we in the United States have about 2000 members. That's created a whole community of scholars and tremendously tightly wound community.

The other point I would make as far as emulating things is I think ethics committees, clinical ethics committees, if you look back historically have been more successful in integrating themselves into the fabric of hospital and clinical life than IRBs have because they have been collegial, they've been consultative. They followed a medical model versus a kind of legalistic model, and I think maybe if IRBs were more like ethics

committees, like our European colleagues, perhaps we'd be more successful.

**DR. GUTMANN:**

Jim.

**DR. WAGNER:**

Just a very quick question, Joe, I wanted to take you up on your challenge around surrogate consent and ask if, how you know you have drawn the line if surrogate consent is understood as giving consent for people who we judge are otherwise unable to do so, that seems dangerous. If we say it is for folks with a specific clinical diagnosis, vegetative or minimally conscious, perhaps that is safer. Is that, you see my fear, right? If we decide that there is a certain group of people who are for whatever reason unable to give informed consent that we would authorize someone else to serve as a surrogate seems like a dangerous practice.

**DR. FINS:**

Right. Oh, okay. So I mean, we do not want to stigmatize a group of patients by virtue of their diagnosis. So the mentally ill, for instance, are presumed to have the capacity for enrollment in clinical studies. They are not categorically excluded. It really hinges upon the notion of decision making capacity, on which there is a robust literature about people understanding the risks, benefits and alternatives, the consequences to them. But, so there is, that line is drawn routinely in clinical practice, when we turn to others to consent for you or to authorize treatment or when people are in the research context.

**DR. WAGNER:**

The illiterate in portions of the world, and I mean scientifically illiterate, I don't mean necessarily unable to read and write, one might argue, this is where I think you get in danger, one might argue that such people are unable to understand the risks, and I'm not sure I'd be comfortable assigning surrogate consent.

**DR. FINS:**

In the Nicomachean Ethics, Aristotle talks about what is owed to each other, and the greater owes more to the lesser and if somebody does not have literacy to understand what is being described, the physician or whoever is getting consent has a moral obligation to make it understood. So people talk about the literacy level of consent forms being written at an eighth grade level, if people need assistive devices, our patients, some of whom are in a kind of locked-in state. Jean-Dominique Bauby, you know, who wrote *The Diving Bell and the Butterfly*, at first glance, lacks capacity, but he wrote a brilliant book. If he had the right tools, the right

prosthetic intervention. So our obligation is to meet people where they are. I agree with your concern.

**DR. GUTMANN:**

Let's thank once again Joe and Ron for wonderful [applause].