



Presidential Commission
for the Study of Bioethical Issues

TRANSCRIPT

Commission Members

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James Wagner: We're going to continue our session or meeting by talking about human subject protections as professional standards. We have heard in meetings and public comment that at times there is tension that exists between the importance of regulation to keep human subject safe and the burden that some researchers feel to meet them. We recognize that regulations alone do not necessarily ensure or make for ethical practice. A researcher embodies research ethics as a professional code will carry those ideas into the work whether it's mandated as a condition of federal funding or simply a matter of moral propriety and rectitude. To get us started on this discussion, we're going to turn to John Arras. John will be representing one of the several study groups that we've had working. This will be our pattern throughout the meeting to let all the commissioners comment; hear from groups on which they may not have served and to be able to comment. So John, when you're ready, I'll turn the discussion over to you.

John Arras: Okay. Thank you very much, Jim. I'm on a committee with Steve Hauser and Alex Garza. Alex can't be with us today. I—my charge here is just to get the ball rolling on some of the central points that we make in our section of the larger report. We can do this dialectically. We can begin with the doctors in Guatemala: Dr. Cutler who viewed, I think it's fair to say, viewed the constraints of research ethics regarding informed consent and so forth as just so many obstacles to the kind of work that he was interested in doing. He wanted to keep his work secret. He viewed surveillance by outsiders as interference by do-gooders. Right? So he obviously viewed the norms of research ethics as obstacles to doing research. At the other extreme, we cite in our section here, Henry Beecher, the famous whistleblower who was sort of a transitional figure in the history of research ethics. Beecher was the great whistleblower publishing an important paper documenting the lack of informed consent. Beecher, however, was against the imposition of external law-like regulations to the process of research ethics. There is a wonderful line in one of Beecher's articles where he says in addition not informed consent really the best safeguard for the individual subject is what he calls the intelligent, informed, conscientious, compassionate, and responsible investigator. So Henry Beecher viewed a kind of virtue ethic as the solution to the problem without the need for external regulation.

His hope for that sort of a regime was dashed in the years immediately after that with the revelations of Tuskegee and a host of other scandals which proved the necessity of regulation, and that brings us to the common rule and the present day where we have both a system of regulation and also hopefully a system of lively professional obligations sustained by professionals as part of their identity. So the worry is, and this is a worry that's been transmitted to the commission on a number of occasions by people giving testimony, the worry is that the norms constituting research ethics are often today perceived as onerous obstacles to research. There's a kind of hyper-regulation, and so there's a worry then that the norms are not being seen properly as a part of the professional identity of researchers. What it means to be a researcher would be to embrace these norms. So in our section, we advocate two different responses to this. Some clever person on the staff came up with interesting language of pruning and budding.

Male: The gardener.

John Arras: Who's the gardener on the staff? So with regard to pruning the idea is to prune away a lot of unnecessary or unnecessarily onerous regulations which it is alleged give the regulations a bad name. Ditto for certain kinds of training which are perceived by various parties as being onerous. One of our testifiers called them insulting. Right? So the pruning phase is to

try to pare down the system so that the system will elicit more respect from those that it governs. The budding phase is a bit more amorphous. The budding phase really is a kind of open ended encouragement. Everybody has a piece of this system to work together to find better ways to help professionals internalize these norms. Right? Not just through regulation, but through collegial mentoring or other better ways to educate people. Finally, we have a much more discrete recommendation which is that the common rule should address the actual responsibility of investigators. In other words, the common rule should not simply address itself to the responsibilities of institutions, but also to investigators themselves. Some of the people around the table have been talking about what they've learned today. This is something that this never struck me. I never really realized that the common rule was not actually addressed to individual researchers. Apparently it's not. So we advocate that the common rule does include a new section discussing professional obligations. So that's basically what we've come to. We're really appreciative of any comments that you might have.

James Wagner: Remarks from around the group. Yes, Christine.

Christine Grady: It's really a question—

Amy Gutmann: May I ask everybody. Although we can hear each other, it's really important to use the microphones so that everybody in the back can hear us.

Christine Grady: Okay.

Amy Gutmann: Whether they want to or not.

[Laugh]

Amy Gutmann: We're obligated to enable them to do so.

Christine Grady: It's really a question I think John you talked about it with respect to one of the pruning issues and that is making training programs more—I don't know what the right word is—more powerful. Less check-listy or something like that. Less mind numbing and I'm wondering if we have any thoughts about how that should happen? How do you internalize the norms? How do you teach people to internalize the norms?

John Arras: Yes. If I could just expand on that a little bit. I mean I worked in a medical school for fifteen years at the Albert Einstein College of Medicine in the Bronx and from my point of view we're talking about the internalization of professional norms. I saw how this was done very close up. Mentoring, you know—senior faculty mentoring junior faculty over a very long period of time. That's how it was done. Now the problem that we have here is that we have huge numbers of researchers. Huge numbers of research projects and this kind of imparting of a spirit of professional responsibility has to be done on a massive scale. That I think is the crux of the problem. We have huge numbers of people and we have to think of ways to educate them that achieve the same results as the old fashioned system and ways that might be more efficient.

Amy Gutmann: So, I wouldn't look back to any golden age where professionals internalize norms. I think what we're seeing here are two either complementary, which is what we'd like to make them, complementary or conflicting ways of furthering professional ethics and they are to have a set of robust rules to guide anyone who has the right and privilege to do research on human subjects which we have a responsibility of a society to enforce. And internalized norms of professional ethics without which it is almost impossible to have a set of rules and regulations, as much as the founding fathers wanted a constitution that would work even for devils. No constitution and no set of rules works even for devils. And nobody thinks that our professionals are devils, but even if they simply don't take ethics seriously there can be problems. Right? So we're trying to do both and we have gotten to a point. We've heard from lots of people that the rules and regs go beyond—I mean—they're so complicated and so—they're not harmonized sufficiently to make any ethical physician think oh, they're fine. So we have to prune. We have to advise and that's what the AMPRM is trying to do. Try to get more harmony so that ethical professionals feel that they're being supported in their task and able to produce medicines and other really important products with ethical research. At the same time and the question you asked—so I'm getting to my answer to this is how do you internalize—how do you get more internalization of professional standards. I think it is too late to wait until people become researchers and doctors. It's not that you shouldn't do it there. You should. I think we need a more robust sense of the teaching of professional ethics at the undergraduate level to people who will not only become doctors, but to people who will be affected by doctors in their life. So patients as well as doctors understand what the ethics of the profession is. That's not something that the government can mandate. It's something that we as a commission can say is sorely needed in our society and in our educational system.

John Arras: Thanks for that plug. This is what we do at UVA.

Amy Gutmann: We do it and we need to- all colleges and universities I think need to do it more. But that's just a very—I think that frames what is an important recommendation, but I think the recommendation is going to have to go beyond what can be done at the level of the professional researcher one step person is doing the research.

John Arras: Actually Nita is next.

Nita Farahany: Amy, I thank you for those comments. I agree with you. The more specific we can be with giving recommendations about how to do that and thinking at earlier phases is somewhat helpful. We made similar recommendations with synthetic biology about the internalization of norms. And I've been working with a group called the human practices group of Synberg which is seeking to do just this which is to develop norms for synthetic biology more generally. I think that's a laudable effort which is really terrific that they're doing so. They're struggling because they don't have—at first—they are at later stages of development. They are post grads, post docs. People who are in later phases of their careers, they haven't had the earlier interventions. They also don't have a lot of guidance. They've been looking for outside guidance on how do you actually build norms that can be internalized and how do you do it within that field or in any field and I think that to the extent that we can brainstorm some more ways, including education at the undergraduate level and provide ideas for researchers and ideas

for you know more generally how we expect this recommendation to be achieved. I think that would be incredibly helpful.

Amy Gutmann: Let me give you one very specific recommendation which—and there's a good body of evidence. This is one of my fields in educational research that this works. Our report on ethics—entitled *Ethically Impossible*. The report on Guatemala could be made into teaching modules. Teaching case studies and what we as a commission have learned from those case studies and we hope society—members of society will learn we could make that so it's teachable at the high school level and at the college level. And that's just one example. There are many other case studies that could be developed as well. There is good evidence that when you engage students at every level and this includes the level of doctors and professionals with actual cases where they have to say what would I have done in this case? How can I understand what was done in this case? How do I have to act and think in cases like this? That works very well. I think we can make a very specific recommendation that ethically impossible and other case studies actually be taught.

James Wagner: Absolutely. It certainly helps in part to ensure people know what to do. The real drill is to get them to do it. Lonnie.

Lonnie Ali: One of my frustrations in some of these things is that a lot of what commissions have proposed in the past and a lot of government convened agencies groups have proposed never gets implemented. I'm always looking on the lay side of how do we actually make this happen so that everything we do here is fruitful. Just to expand on what you said, Amy, you know these modules you're talking about—I think it's the rubric that a lot of morality courses are taught, but it's still an elective. It's not something that's required for these children to take or for college students to take. I don't even know if you could answer this, John, whether it is a required class or course in Medical School. I'm not sure.

John Arras: It is in Medical School.

Amy Gutmann: It's not required by the government.

Lonnie Ali: No, no.

Amy Gutmann: Most medical schools require a medical ethics—

James Wagner: Because the profession requires it.

Lonnie Ali: Given the way we operate here and trying to make these robust recommendations, I think it's important to take that into consideration that it may not be an elective. It may be something that should be required of people who go through these institutions.

John Arras: And it's so often done as a standalone adjunct instead of part of the core. Raju.

Raju Kucherlapati: John, thank you for all of the efforts so far. We talked about rules and regulations. And talked about the fact that the central theme of the importance of ethics is sort of

hidden now by virtue of these larger numbers of rules and regulations and I think that we should make that point very clear. The second aspect is that is it sufficient for us to make a recommendation to say that we should prune the regulations or do we need to be more specific about what are the specific areas in which pruning would be helpful. If we just say prune it. That may not have the same kind of impact unless we give specific examples of how things can be changed that would make people go back to the ethical principle and still be able to conduct, promote the kind of clinical research that would be beneficial for human kind.

Amy Gutmann: Could I just answer that on behalf—

John Arras: Sure.

Amy Gutmann: Of the larger project. I think Raju is absolutely right and I think what we should say in professional standards is we need to—we ask for an exercise and we'll give examples in the report of where we think there can be pruning and the examples will come and I—and I think one of the places it can come in addressing Lonnie's very important concern which is there are reports out there in the past on similar topics where we see no response, by which response I mean not even a response—

John Arras: Of anything.

Amy Gutmann: Of anything. Right? I think now with the ANPRM exercise, there's an opportunity for us to be very specific about some places we think should be—there should be pruning, and how it should be pruned.

John Arras: Right.

Amy Gutmann: You can prune and something—to use this metaphor, something more vigorous can prosper or you can prune and kill. We don't want to kill important rules. We want them to actually be stronger as a result.

James Wagner: I think it's important if and when we check in that way that we be very clear of the purpose, John, that you said, to restore respect and that Raju, you said, to reconnect the regulations to the ethical foundation. There is no dearth of a number of lists from other organizations also responding to the ANPRM specifically on the onerous nature and redundant nature of some of these and we can certainly look at some of these listings including lists produced by the AAU schools and we may want to opine on those, but I think what would be—the point we will need to make in that response is that we are focused on the ethics as we are here in the next session, that we're focused on the ethical dimension and not just the burdensome dimension which is what most of the others are responding on burden of cost and effort. And we're responding on the connection of the ethical foundation. Steve.

Stephen Hauser: One of the words that I most like in our report is lively. How do we institutionalize a lively culture of ethical thinking around the hospital and around—all of the professional organizations and I was very taken by Gawande's argument in the New Yorker early this fall about the importance of coaching for even very senior people. I wonder if the

educational standard that we require for our trainees might also be incorporated for the gray hairs in the—in our professions. How can we stimulate an ongoing ground level continuous discussion through seminars, through special sessions that would focus on detailed questions that might not reach the IRB level?

John Arras: Good question. Dan?

Daniel Sulmasy: On the budding side of things, one place that we can—

Amy Gutmann: Dan, use the microphone.

Daniel Sulmasy: On the budding side, one place where we can have some leverage would be to work with accrediting bodies like the for instance, not all the government requires this. If you want to get into educational systems, the liaison committee on medical education has standards for medical schools. To the best of my knowledge the education and ethics does not require anything on human subject research ethics and there's an exposure to research, but I don't think there's anything about research ethics. That might be a place to move on—

Female: That's.

Male: Wow.

Daniel Sulmasy: Or similar and similar kinds of organizations. We're not just talking about medical schools here as we know from our landscape project. That might be a place to go. Second in terms of working with the kinds of strategies we have. I don't know who we should engage, but I think some sort of systematic study of best practices for research ethics education so that it could be disseminated would be extremely valuable. We could all anecdotally say what we've had. What we do know is that pamphlets, you know however nice they are, don't work. Online courses actually as we've heard from testimony actually undermine the sort of sense of ethical responsibly and can make it onerous for a lot of people. We've got to find what the practices are and I don't know if we in our little forty minutes talking here together find that but we can figure out who to conduct such best practice study and I think that would be very valuable.

Amy Gutmann: By the way, if anyone in our audience here or participants has a question or a comment, please, the same holds with cards. Thank you.

Christine Grady: I'm sorry. A little suggestion along the lines of what Steve brought up. There is a model that's developing. I think it started primarily or got a lot of encouragement through the CTSA which is an NIH funded network of institutions. And people—institutions that hold awards through the CTSA program are developing research ethics consultation services of various sorts. There are no standards. There is no one model at the moment, but I think the way that most of them work, at least my familiarity with them is exactly what you are describing. It's an opportunity for investigators and others—IRBs sometimes call for help. You know to have a discussion about what the difficult issues are that are not formulated in the regulations, but come

up in so many research projects. And so maybe some kind of recognizing that kind of a model as one way to allow for these lively conversation and discussions would be something we could do.

Amy Gutmann: Wonderful, Raju.

Raju Kucherlapati: Christine has made a point yesterday in a different forum and she said that all of the people who are engaged or would engage in clinical research should be thinking about the ethical values right from the beginning. Not at initiation of a trial or some other time, but right from the beginning and I thought it was a great idea.

One thing at least I don't know what other institutions. Here for example, you know we teach all of the graduate students and the title is responsible conduct of research and it should be ethical conduct of research because the responsible conduct of research is a subset of ethical principles.

Female: Yes. Yes.

Raju Kucherlapati: I think I guess what I'm trying to say is we do not emphasize ethics enough. The word "ethics" not enough.

Female: No.

Raju Kucherlapati: They may be embedded in what you're trying to teach them, but if you think about the ethical conduct that might be very beneficial.

Amy Gutmann: Good point.

James Wagner: Good conversation. I think we had some input on both facets. Pruning and budding. For you and Steve and Alex to work on. Do we have a comment?

Amy Gutmann: Okay this is a segue but we'll segue with a comment.

James Wagner: Since we have someone—Stephen Marks. Stephen, I'll tell you what—given the length and compression of your handwriting, would you mind coming—

Amy Gutmann: Stand up and turn around and address the-

Stephen Marks: I condensed it as much as I could. Thank you. This relates to some of your precious work and previous reports regarding the standards that you're applying and the way I put it is this. Universally recognized human rights in quotes, because it's directly from your report, are used by the commission only to exclude some cultural practices from visiting informed consent. That's the only place I could find the use of universally recognized human rights, and yet informed consent, freedom of scientific inquiry, social justice and a number of other ethical principles mentioned in your reports and in the discussion today are also universally recognized as human rights that are also treaty obligations of the United States. Why does the commission not refer to human rights standards binding not only in other countries which you do

refer to? But also binding on the United States—are not human rights. Relevant to the quote harmonization of transnational standards and universal principles which is part of your mandate.

Amy Gutmann: I'll begin and it is not out of disrespect for human rights standards that we don't mention that term more often. Rather, we think it helpful given that there isn't an authoritative statement of human rights, but many statements, we thought as a commission that it was most helpful to enumerate the ethical principles that we believe and in harmony with human rights standards we believe should govern the ethical conduct of research. And so we set a set of principles which is in harmony, we're happy to say, with the Belmont report, for example, but goes beyond it including public beneficence. You know them. They're in our reports, but they're a set of ethical principles that are also in complete harmony with human rights standards. We—there are different languages that you can use. As somebody who is trained in moral and political philosophy, I'm well aware that depending on what theory of justice you defend, there are different set of languages that you can use for this. But by and large, not entirely, but by and large, they are consistent. And certainly with human—there's everything we say in our previous reports is consistent with standards of human rights.

Stephen Marks: I was referring to a treaty obligation of the United States. Legally binding treaty referring explicitly to informed consent. Article seven—

Amy Gutmann: Yes.

Stephen Marks: Of the political rights as you know.

Amy Gutmann: Yes. But we—

Stephen Marks: More than just a choice of—

Amy Gutmann: No. No. It—I—what I said, I'll just elaborate then on what I said. We defend informed consent. As an important standard, ethical standard of research and we have not and will not retreat from that.

James Wagner: I'm not going to let you segue just yet because we've got another quick question.

Amy Gutmann: We're going to—

James Wagner: I'm sorry. This is from a student actually, Ilana Yurkowitz. She writes: I'm a first year medical student, so the topic of ethics education resonates closely to me. Many schools, including Harvard now require ethics courses for medical students, but disappointingly, many students see these courses as soft or fluff and do not take the courses as seriously as they should and do we have thoughts on combating this attitude issue. We also have investigators—go ahead.

Nelson Michael: I'll provide you an anecdote that might provide you that relief. I had one hour of ethical training during seven years at Stanford. So it's—exactly.

Amy Gutmann: But that was in the nineteenth century, right?

[Laughter]

Male: That was in the Pleistocene era.

Male: The wheel had just been invented.

Nelson Lee Michael: But being a member of the Army, we love to train and train to standard and sexual harassment training is something that we used to do in the military once a year but now I do it four times a year. And I will tell you that I've gone through a number of different modules just seems to be something different and it tends to be formulaic and it tends to be something, just like the student mentioned a lot of soldiers don't take it very seriously because of the way it's delivered. It's delivered by some bored sergeant to a group of bored group of soldiers and they realize it's something they have to do. For the first time, three months ago, I took an online module that actually was based on—you're going to love this. It was based on cases. So you chose who you were going to be. I chose myself to be a female sergeant and you were given a series of videos and based on what your answers would be—what should you do next. What was the right thing to do as an observer or as that person? You would follow down a series of different pathways. I found it and again I'm doing this four times a year. It was the first time I really struggled with that topic and found it enormously helpful. I think the more interactive training can be, especially when it's something that you have to do and people don't take it all that seriously. I think there are effective ways to make that cogent and in my view an interaction and case based learning I found very effective.

Amy Gutmann: We really need to segue otherwise we're not going to have time.

Male: The boss says we're segueing.