



Presidential Commission  
*for the Study of Bioethical Issues*

## TRANSCRIPT

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**DR. GUTMANN:**

Many thanks to everyone. And I would like everybody who has presented today to give us some of their advice and then we'll open it up to questions.

Let me just frame this with President Obama's charge to our Commission. And his charge was, and I'll paraphrase, but it's very close to the actual words. To assure him that current rules, and international standards, and by that I'm sure we are to understand operative international standards, adequately guard the health and well being of participants in scientific studies funded by the U.S. federal government.

And I understand none of you is coming here as an expert on the U.S. federal government funded research. That's our job. But it would be helpful, very helpful, for us since what got us here, the propelling cause, although it is not, it doesn't subsume our goal in this, but the propelling cause is the exposure of U.S. government funded research in Guatemala and we're now looking forward. Our commission is taking a forward looking what exists now by way of rules and operative standards of government funded research overseas, or international. It's not necessarily overseas. So the question, and I know you've been warned that this would be the question, in the sense that I want each of you to give us one single issue that's relevant to this charge, that you think we should make sure that we focus on? One single issue in the panoply of what we need to take into account to assure or, I want to just make clear that we're not going to assure the President if there is no assurance to be given, but rather to advise what needs to be done if that assurance cannot be given. And, again, standards, rules and standards, to adequately guard the health and well being of participants in scientific studies. So, John, may I begin with you?

**DR. ARRAS:**

Yes, thank you. I'm going to state from a perspective that hasn't been heard in the last couple of days, and that is as a member, and in fact, a chair of a research ethics committee. We had a meeting just two days ago, so a lot of these things are still fresh in my mind, and I'm thinking of this from a perspective of a committee. And I want to go back to Christine Grady's opening presentation where she talked about one of the challenges in this whole exercise, and that's burden. You talked about the burden of, on researchers and so on, but I think you should consider the burden on committees, and committee members, and the institutions that support them.

So there is a lot of dimensions to this that really need to be considered. It's a tough job right now being a committee member. It's a tough job recruiting new committee members.

**DR. GUTMANN:**

You're talking about IRBs?

**DR. ARRAS:**

Yes.

**DR. GUTMANN:**

What we call IRBs? I understand that.

**DR. ARRAS:**

What you call IRBs, yes. Yes. And I think that any ... future to the system, any recommendations that you make should take into account its impact on IRBs and their membership and the institutions that support them, because this is also a burden on the institution. And in particular, if I could just mention this one thing, if the IRBs are not simply to be checklists for compliance to basic requirements, or standards you might call them, but are really to the ethics committees, they should have the authority to request, or even demand, that researchers go beyond the minimum standards that you might want to identify that are common to all the documents, and to have the authority to require higher requirements.

For instance access to benefits. Which you may or may not want to have as part of the minimum standards for research on human subjects, but it was certainly something that's evolving as a very desirable thing, and the ethics committees' research IRBs should at least I think have the authority to say that even though you meet the minimum standards your research is not going to be approved unless you provide higher benefits or fulfill other conditions than the minimum standards.

**DR. GUTMANN:**

Thank you. Maurizio?

**DR. SALVI:**

Yeah, two really telegraphic suggestions. First that whatever is proposed you need a mechanism to monitor that it's implemented. Then an auditing process. And also a possibility with also legal power capacity to verify that this is carried out during and after the clinical trial systems. They are not starting at

the beginning, but also during, otherwise it will be a nice description which is not corresponding to reality.

And the second one, coming back to the research ethics committee issues, the need of capacity building in local, in the country where the research is carried out. Not only going for the use of the proposed ethic standards, but for the assessment with local characteristics in social and cultural considerations of the standards being proposed.

**DR. GUTMANN:**

Okay. Linda?

**LINDA NIELSEN:**

Yes. I think that the protection which is based on the harmonized basic regulation, and then lay out so that you have some provisions that can be seen in context. And then to harmonize and simplify.

**DR. GUTMANN:**

Thank you. Francis?

**FRANCIS P. CRAWLEY:**

I think I said it already. Transparency. And I think with regard to this U.S. funded research, I just want to say that not only in Europe, but also I've done a lot of work with capacity building and other things in Africa and Asia, Eastern Europe and so forth. And the U.S. has really a leading role. They're really well looked up to and they, the U.S. lead is very important here. And I think with regard to transparency, one of the things we can strive for as well is transparency with regard to the rules themselves with regard to the regulations themselves, to clarify those, and to make it easier for people to understand them and to implement them. Thank you.

**DR. GUTMANN:**

Very helpful. Thank you. Dafna

**DR. FEINHOLZ:**

Yeah, well, I wanted to say it this is very relevant, although I was not present yesterday, I have been part of the discussions, also I've been a member in some committees here in the United States and other places, that this reflection on compliance and ethical evaluation is really relevant, because even if you have lots of regulations, and even if they are harmonized, you can always find way to have a good explanation of why you are making an exception.

And then it could be then possible even to have another Guatemala. So I wanted to say I really think it is important that ...

**DR. GUTMANN:**

If someone has a Blackberry near the microphone. Just move it away, please.

**LINDA NIELSEN:**

I don't know if it's mine.

**DR. GUTMANN:**

Sorry, go ahead.

**LINDA NIELSEN:**

So this is one of the most important things for me, it's like trying to make sure that there are ethics in the regulations. And so one of the basics, if I had to say one big thing, coming back to Article 21 would be really promoting this dialogue and this collective thinking and collective harmonizing of regulations which will include the local views on the ethical perspectives, ethical values, ethical health needs, and that would be a way to ensure that everybody's represented. If everybody is collectively building them.

**DR. GUTMANN:**

Thank you. Hans?

**DR. VAN DELDEN:**

Being the last speaker in this row it's difficult to say anything intelligent. I don't think I understand your question as asking what guideline exactly you would like to work on? Because I don't think, well, it's my perspective, I'm not sure that you should aim it writing the guideline that ends all discussion. I don't think that's going to happen.

If I look at the research ethics from an academic perspective right now I think the question that Christine put to us, how to balance individual interests and community interests. And what exactly is meant by former guideline five, now six, in the Declaration of Helsinki, how to interpret that. Those are basic issues that maybe could be furthered a little bit.

And indeed as often said, I would call it community consultation because that extends through the whole process. It starts before the research is started, but it also extends to after research in terms of what consists of fair benefit sharing.

So it's the balancing of individual and community interests and community consultation.

**DR. GUTMANN:**

We're open to questions. Raj?

**DR. KUCHERLAPATI:**

I wanted to pose this question to everybody, and throughout the discussions today and yesterday a lot of people talked about individual rights, and community rights, and how we should take that into consideration.

And I wanted to understand a little bit more about community rights. How do you all define the community? Is it the town, or a small city? Is it a country? Is it the world? Because the implications are obviously depending upon how you define this are very important in terms of how do you think about that. On the one hand when you think about the Helsinki Declaration or something, we talk about universal rights for everybody in the world, not to just the population in one country, or one small region at another. And yet sometimes when we talk about community rights, we're talking in a very limited context of a small group of individuals. And I would like to hear about how you all think about that.

**DR. GUTMANN:**

Yeah. Are we talking about community rights? Or if not, if we're not talking about community rights, you did mention community consultation. So ...

**DR. KUCHERLAPATI:**

So I ...

**DR. GUTMANN:**

Go ahead. You're on the hot seat.

**DR. VAN DELDEN:**

In a way you just threw the question back to me, which I posed to you. But you're perfectly right. This is a big problem. What exactly is the community? Is it just the participants? Is it a group to which these participants belong? Or is it the country? Or the region in which this study was performed? And it's not at all clear. So I apologize but I don't have the clear cut answer.

**DR. GUTMANN:**

Could I just throw up so we can be specific on this, because it's a very, it comes up in all the lines. Let's just be specific; as far as we know, in Guatemala, in the Guatemala case, the Guatemalan government agreed to this experiment.

As we know today getting the agreement of governments to experiments is no guarantee for sure of, it doesn't even in many cases pose a very high bar, right? So what is, I think Raj asks a very, very important question; what is the value? Can I ask you this? What is the value you see in community consultation? And at what level do you think it's important? Practically speaking you can't generally go into most countries without the country consenting, that's a practical consideration. But what's the value here of the term community consultation? Or the things that mean the same, in effect mean the same thing? Francis?

**FRANCIS P. CRAWLEY:**

Thank you. When CIOMS was rewriting its guideline in 2002 or 3 or so, a few years ago, they assigned me to write a chapter on community event, which I did from somebody from Morocco.

And I think that what we have learned really is what we justified, the way we justified medical research predominantly was through consent. Not a simple consent, not to just say yes, but informed consent.

And, I think what we've learned over the course of time is that this consent doesn't involve only the individual person who is being invited into the research, but also where the research is taking place, and those who are affected by the research, and surrounded by the research.

So really what we have, and I'm sorry to come back to it, but it is transparency, because with consent we have a first level of transparency. A first level of opening up to say this is really what's going on here. And then we have moved this into a larger level towards communities more recently to say this is how you're being affected by it.

And it's not only communities that we should say in developing countries, we also do this, for example, in Europe, or in the United States, for example, HIV research and so forth, we approach communities at that level as well too.

So I think why we do this is because it is more of an opening up and an addressing of those who we see as being directly involved with the research.

**DR. GUTMANN:**

John?

**DR. WILLIAMS:**

I think the question that you raised is different from the one that he raised. You wanted to define community. And I think that's important, but also community consultation obviously an important issue too.

As far as defining community, I think this is an evolving concept, and I think it's so varied that it really does differ from one environment to another. It's pretty far advanced in Canada with regard to aboriginal peoples. And in the latest edition of our national tri-council's statement on research ethics, there's a very long chapter on research on aboriginal peoples that has been many, many years in development in consultation with representatives from the various aboriginal groups.

There is also a fairly well developed definition I guess of communities in some African contexts where a tribe, or a clan, is pretty identifiable with a recognizable leadership. And so it's not difficult to say who the community is and how that community could be approached.

It's more difficult in the United States and in Canada where there are large immigrant populations, some of which are very cohesive. And if you want to do research on a particular group, or a particular immigrant community in this larger sort of situation here, it's very important to talk with that community and I guess to define it, and that's going to be on some situation in front of another. So I think the answer to your question is that really it's very important to consider who the community is, but it could be very difficult to determine, it could be easy to determine in some situations, very difficult in other situations. As far as consultation is concerned, does that mean getting the approval of community leaders? Or of all the members of the community? And again that varied so much from one situation that I think it's impossible to provide hard and fast rules.

But it is a consideration that researchers should take into account. Not only for the purposes of informed consent, but actually that was pointed out in order to get permission and buy in to the research from all levels of the community.

**DR. GUTMANN:**

I think underlying both Raj and my questions really was to try to figure out what you see as the value of this. I mean, we know what the value of informed consent on the individual level is. Is there one value? We could come back to this, but ...

**DR. WILLIAMS:**

There's a pragmatic value of having permission to do research. That's certainly important.

**DR. GUTMANN:**

That's certainly the case.

**DR. WILLIAMS:**

But I think the larger value is knowing the group that you're working with, and not assuming that your approach to, whether it's the physiology of the contingent, or the social circumstances, that works in one place will work in another place.

**DR. FEINHOLZ:**

I also wanted to say that I understood the different questions of different meaning. So I would follow up on what John has just said and go back to that it is true that it is really difficult to define communities, and I agree with him, with those who are already more easy to identify. But you could also speak about the community of HIV people and that would be if you are conducting research on HIV, you can also think about that as a community and what the benefits are going to be. And so those could be the ones to be consulted and not particularly ethnically. So it's not, it's really not so easy and it's important to take that into account. And on the other hand is the consultation at the community level for conducting the research, which I think the added value is also more involvement, and as I was saying before, knowing better if this is responding to what the needs are. I think that would be one of the other values.

And then there is another level of consultation that I was thinking because you mentioned the government. So that is a different level of doing a consultation at the community level for actually conducting the research, but to do the agreement. So who is deciding on the other side? On the agreements? So the idea is, I think, there is some projects being there also trying to be pushed, that it would be, I think, something for the international community to do, that every country should be like a community, a group, of different stakeholders, that make these decisions.

Because that's what I said, for example, when I said, of course, our government can agree to our research, because it brings its resources to the country. And that doesn't mean it's protecting, or this government is accepting because other good reasons could be there.

So that's why should be probably larger group of stakeholders even in the country to make those decisions.

**DR. GUTMANN:**

Thank you, Raj, would you like to ... I would just be interested in what ...

**DR. KUCHERLAPATI:**

Yeah, I think I should maybe refine it. I understand communities the way John has described it, and we understand that. The question is not about that. The question really is when we think about benefits, accruing to the community, how would we considered that?

For example, if you were developing a drug, and if you go to Eastern Europe, you go to China, India, for example, to look up for a clinical trial, do we consider only those particular regions, or communities, in which those trials are conducted and considered benefits for them? Or do we consider the benefits for the world as a whole? Because such the development of such a drug would benefit perhaps everybody.

So there is a distinction between the two because clearly some people would make arguing that you should just think about the benefits for that particular group of people, ethnic group, or national group, or whatever the group is, and how you will benefit it, as opposed to benefit for the entire world. That's the question that I was trying to ...

**DR. GUTMANN:**

And the population.

**DR. KUCHERLAPATI:**

Okay.

**DR. GUTMANN:**

John?

**DR. WILLIAMS:**

Well I think the ethnical pinch was that those who undergo the risk of research have a prima facie, not a right, but a call upon the

benefits of the research. So if there are benefits. So whether it's individuals, or whether it's a community, there is kind of a basic ethical principle. Now how that's going to be applied in any particular situation, and how that community is going to be defined, and what sort of benefits there should be, these are all questions that have to be worked out on a case by case basis. But on a larger basis, I guess, the whole question that we're discussing here is evolving. I think, you know, ten years ago, or twenty years ago, as far as I know, this wasn't an issue. This wasn't really considered. Now it's just being part of the ethics debate. But, you know, like many ethical issues, it takes a long time to formulate the question, and then to start to come to some resolution of it. And I think we're a long way from coming to a clear understanding that everybody can either accept or reject as to what's required here.

So in terms of who the community is, I think again, it's sometimes easy to identify, if it's a particular tribal region in Africa, for instance, and it becomes very difficult. But I think in between the individual and the world there are identifiable communities that we're talking about.

**DR. GUTMANN:**

I'm going to move on. We can carry on this important discussion more. Dan?

**DR. SULMASY:**

I've been listening through the whole morning, and it seems to me that one of the, what we're after in the end is not exploiting subjects, right? This is what we're really after. And the ways in which it seems we can get international agreement, or where we have all of our standards, what might be necessary standards, all become process standards. Transparency, committee review, and even informed consent, those kinds of things.

What we really want are the definitions of things that we've heard about before; rights. What is risk? What is fair benefit? Fair subject selection? What's a benefit to the community? And we can't really get it, seems, international agreement on those kinds of things. And we're sort of settling for these processes to do it. And the hook we might have is the funding source, and the sort of standards of the nation that's funding it, or the organization funding it. But then again if it's done in an international cooperative way there has to be another process which is negotiation in fair respect with the host nation, which again is still a process, and may have vulnerabilities there because of the lack of ethics infrastructure, the different understandings of these

substantive concepts like rights, poverty and sort of lack of educational opportunities for potential subjects, that give them the possibilities for exploitation, even within the system that we've been setting up.

So and then coupled with, it seems to me, insufficient capacity to monitor this. It seems to me that's the vulnerability within the system. And I wonder if you agree. And then if so what can we really do to shore it up?

**DR. GUTMANN:**

Linda?

**LINDA NIELSEN:**

Well, I do think that you are right in the sense that most of the things that we've chosen are processes. On the other hand I've tried to go through all the different kinds of regulations we have in this area, and what we more or less say we won't have, you can also phrase it as a right to be asked. It's a right not to be this and that. So you can phrase it as rights.

The things that we do not want, that is to include inproportionate risks, risks that are not open and consented to, and unscientific conduct. So if you want to say what don't we want, those could be the things, but I think that it's much a matter of phrasing, I could easily phrase much of the things we've talked about as wise.

**DR. FEINHOLZ:**

Well, I think I would also agree with what you've said, but I think that it's one of the most important things, or challenges. As In fact I tried to introduce in my own presentation, but I would say that this is also, as we were saying, about how to introduce the issue of community and how to build the benefits of commitment, that's something that we still need to develop collectively. And I do think that it is a value, if we already decide that we have to build this answer collectively, I think this is already a value and not only a process. How do you find the process is also a charter, and an ethical value, and I would say that there is also already another value if you discuss with those countries which doesn't has those notions. Because that is, it's a way to alert them and to start the process.

So I think there is already doing some collaboration in that. But it is also true that it will not solve the immediate problem of that particular project. That is also contributing too little.

**DR. FARAHANY:**

So this is directed in part at Francis, and anyone else, but I've been mulling over the concept of transparencies, you've introduced it, and this really builds on Anita's question earlier to try to understand what the value is that you're seeking to promote by advocating for transparency, and also what you mean by transparency. So I'm envisioning that you mean something like all studies would be registered in a public registry like [clinicaltrials.gov](http://clinicaltrials.gov) but on an international level prior to subject enrollment.

And that the positive and negative results of those studies would likewise be published so that we don't have filtering of only positive results being published. But it's the idea that this is an enabling mechanism such that we have ethical dialogue across communities and to Dan's point, it gives us an opportunity to find commonalities and differences at the international level, or is transparency an end goal in of itself?

So it is simply a precondition for us to then find and have dialogue around these studies? Or did you actually have something different envisioned in transparency other than these things that I've mentioned?

**DR. VAN DELDEN:**

Thank you, Anita, and it were indeed, I think Anita's question was really very relevant and I'm still thinking about it. I really appreciate that question very much.

It's really clear that transparency in of itself is not sufficient, and transparency is not the goal. And I would go back to Doctor Reverby here, the goal is trust. This is really important because this is what makes society work.

But I would say you have summarized better than I could've what I would've wanted from transparency. I think you said it very, very well there. It's not a goal in of itself. It's something to be taken into consideration with what we already have. But when I look back at the history of human subjects' abuse, and not just this history, but if I think of ghost writing, I think of people who don't publish all of their results and so forth.

We can do things within guidelines. For me again it's not tinkering with the guidelines now. It's looking for what will bring us to a better place with regard to research.

**DR. GUTMANN:**

Thank you, very helpful. Anita?

**DR. ALLEN:**

Thank you. John, we have, in response to Doctor Gutmann's question, you said that you'd like to address the burden on ethics committees and IRBs. And I have served on at least one IRB, and I know what some of those burdens are. And it's true, you know, some IRBs just rubberstamp research, and some engage in meticulous review of every single detail. And unfortunately sometimes without regard to the complexity or novelty of the research.

But you said that you'd like to, this is a very challenging thing, you said you'd like to see IRBs at these committees authorize to demand higher requirements than just the minimal.

So I want to ask you about these higher requirements. Do you have in mind then moving to the large sorts of international human rights aspirations we've been hearing about today? Or do you just mean whatever internal ethical values the individual IRB member may have? We have not talked at all in the last couple of days about how personal values play into all of this. But I'm imagining that, you know, one way to evoke higher values might be for the IRB members to turn to their own religions and cultures to demand higher ethical compliance in that sense.

Or I could imagine them leaping to shared higher value. So do you mean shared higher values? Or do you mean your national values? Or do you mean something more personal and individual?

**DR. WILLIAMS:**

Well, I certainly meant the former. I think it's the former. Its talk of the value, or the principles, I guess, that are incorporated in ethics documents, like the Declaration of Helsinki, and if you recall in my presentation, I gave a list of issues that are treated in the Declaration of Helsinki that you don't find, at least in present, in the GCP.

And so there are all sorts of things I think that the ethics committee should be able to consider and perhaps even require depending on the circumstances of the research protocol. As far as the individual values, that's a really interesting question. That's sort of on a whole other level. And I guess a quick response would be that in religious based institutions, and still

many of the hospitals, and I guess the affiliated research institutes do profess, or at least are affiliated with a certain religious tradition that has strong ethical values, and I suppose members of research ethics committees could be expected, and they will want to reflect those values in the type of research that's permitted, or not permitted.

But I would be very hesitant about people putting forth, well, actually this isn't, I shouldn't speak too quickly because I'm thinking of some of the committees I'm on, and if people wanted to express their views that are based on religious values, that's fine. But to have kind of a beach hole from, on a research protocol from, because of one particular person's religious views, I think that would be difficult, maybe even unacceptable.

**DR. ALLEN:**

Then how do we operationalize this suggestion of yours that we allow the IRB to demand compliance with higher standards? Do we have a second checklist of international higher standards? So you don't have to follow the narrow checklist, but you have to follow some checklist. It might be the, so how do you operationalize your request for higher requirements to be taken into account without opening the door to personal, subjective, religious, or more local values?

**DR. WILLIAMS:**

Well, I think it's all, it does happen, and I'm sure, you know, without doing a survey of all the research ethics committees of the world, I'm aware of some at least in Africa where they do apply standards, especially access to benefits, and they will not approve research unless there is a component of that particular, but there are benefits coming to the community.

So I'm not sure how this operates in other parts of the world and other committees. But I think it would be easy, relatively easy to distinguish between accepted standards of documents, such as the ones that have been talked about this morning, UNESCO, especially the Declaration of Helsinki, CIOMS, as opposed to what anybody might raise as their particular desire for a particular research project in a particular community.

I think there are normative standards that are found in the international documents that could be accepted without having to take into account anybody, any members of the committee's desires.

**DR. WAGNER:**

John?

**DR. ARRAS:**

Yeah, I want to raise a caveat about the notion of community in these deliberations. Raj asked us to think about community with regard to who gets the benefits of research. I want to focus on community in terms of the question of who consents to the research. Okay?

Really it's a question of who speaks for the community and whether conflicts can exist between those who speak for the community and those who are actually experimented upon. So in our homegrown scandals, like Tuskegee, and Guatemala, we saw that, you know, there was community consultation, you know, as Susan Reverby, is nodding approval here, you know, I can't get a better authority to back me up on Tuskegee.

The local medical society was definitely consulted, and they bought in, and these were largely African American physicians.

The local health authorities in Guatemala were consulted and approved. But in both of those cases obviously there were tremendous and terrible disjunct between the welfare of the patients and the approval at the level of the community.

So, and we see this today in Eastern Europe where a lot of communities see the attraction of pharmaceutical research to be a real benefit to their communities, right? Politicians view attracting research as an important mandate for them. And the result could be, in some cases, a real race to the bottom, right, in order to attract pharmaceutical research.

If pharmaceutical companies know that they could always find a more compliant zone in which to do research, they will probably follow suit.

So do you have any reflections then, on, you know if we talk about community consultation, how do we support congruence between those who speak for the community and the actual needs and interests of the subjects of research?

**DR. VAN DELDEN:**

Can I respond?

**DR. ARRAS:**

Yes, please.

**DR. VAN DELDEN:**

First of all no one is suggesting to replace individual consent with community consent. So of course there should always be individual consent. And I do acknowledge that these are pertinent questions, and the six of us do not have all the answers to these questions, and they need to be asked. But still, and that's my plea for community conversation. I think, well, I think on the research ethics committees, as we call them, for about twenty years now, and most of the time what I'm doing is going over the participant information leaflet, studying risks and benefits, trying to balance that, being advised of the scientific validity of the study and that's it.

No where in this process comes in more justice oriented questions like; is this the right community to study this? The forums that we make the researchers fill in, do not even address that issue. I'm also a member of the National Committee for Research Ethics in the Netherlands, which was supposed to be the authority. They don't even ask the questions.

Just a couple of weeks ago in a meeting, indeed a study in which all research participants actually came from Eastern Europe. I raised the question, everyone looked at me; what are you talking about?

So it's apparently these justice related issues; is it right to involve this community? Aren't we outsourcing this? And aren't we creating new disbalances? It's not really within the framework that we operate from now.

So I'm not telling you that I have all the answers, but I think we are moving away from this individual level in which the primary concern was the individual consent and scientific value, and we have to address these issues. And one way I see this happening is consultation, and because of course I also believe in accountability for reasonableness.

So I do think that in a way that is the mechanism we have to go through. And of course it creates all these questions; who exactly is the community? What authority do they have? Why should they consent? But it's one way, I'm trying to find a way to address these issues.

The present frame of reference is adequate. And I think that is a key issue at this moment.

**DR. GUTMANN:**

Dafna Feinholz.

**DR. FEINHOLZ:**

Just building on what Hans just said, I agree completely with your worries. And I think that absolutely can happen. And just to give you an example of, to follow up on what he did. In Mexico when I was at the National Convention of Bioethics, we issued guidelines, national guidelines for ethics reviews committees, and we included as one of the issues that they needed to take into account when they review a certain research protocol the relevance of the community.

In Mexico we have lots of communities because of the different indigenous groups. And we have lots of people come into the big city from the other states, and many languages. So this is really an issue on everyday life on research. So we did it nationally, not even internationally, but even nationally, why is it important from a national research to go to this particular community? It's the same thing. It's the same question.

**DR. GUTMANN:**

We will come back to this in our deliberations, because it is very important to be clear about what the value is that we're seeking. What's the goal here? Is it to protect the individual subjects? To make sure the community doesn't undermine the value to the individuals who are consenting? Or is it something beyond that about the benefits to people, local people, that go beyond the individuals who are parts of the experiment. So important, but unresolved at this point.

I have one final question from Steve.

**DR. HAUSER:**

Thank you. Mine is a more narrow question. Dafna, you had shown on one of your slides the, I think importantly the goal of harmonizing procedures for DNA and tissue collection. This is obviously an area where there are great differences and including things like opt out procedures for replacing routine consent. And my question is, are there specific areas where uniformity should be sought? And could be done productively given the fact that the terrain continues to change?

And are there areas that a commission, such as ours, could be productively helpful in?

**DR. FEINHOLZ:**

Well, I guess one important thing would be the collection of the tissues and the procedures of collecting the data and the tissues and the samples. I would say that would be. And of course how do you use it afterwards?

And if you are speaking about a collaborative enterprise whether they are using them also would be like how can you ensure that these are in a way also being used in a way that catch others to develop the adequate framework to use it. That's what I would say.