39th MEETING

NATIONAL BIOETHICS ADVISORY COMMISSION

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OPENING REMARKS

DR. SHAPIRO: Let me begin. First of all, I want to welcome everyone to the meeting and once again thank the commissioners themselves for being here today and, of course, our guests. We are very grateful to all of you for taking the time.

Let me just review a few things about our agenda. This morning our agenda is really taken up with two panels of visitors and our discussions with them circling around the issue of the definition of research and the interaction of the various types of research with bioethics. We will introduce our first panel in just a moment but essentially this morning is exclusively devoted to these two panels.

This afternoon we will be turning to some discussions of our own work. In particular, trying to develop a conceptual framework for when it is that the federal regulations or other regulations ought to be invoked when human subjects are involved. That has to do with what we sometimes call the definition of research for the purposes of the applicability of federal regulations.

We will have some discussion on that this afternoon and we will also hear a report from Kathi

Hanna on our survey of the federal agencies and where that is standing at the moment.

Tomorrow morning we hear mainly from the private sector. We will have a number of presentations tomorrow morning. Again we have two roundtables. One representing people from the pharmaceutical and biotechnology companies and one mainly people from research firms.

Again address -- tomorrow morning's panels really address the intersection of two of our projects, namely our oversight project, which is really the focus of today's discussions all day and our international project which we do not have officially on the agenda this time but I think the panel tomorrow morning will touch a number of issues which are relevant regarding our oversight project.

So I think we have a full day today and a full half day tomorrow and I hope that we can get a lot of our work done during this period.

Let me just turn very briefly to Eric to say just a very few things. You have all received his Executive Director's report which was sent to you with the agenda. I will then turn to Marjorie for an equally brief update since that is also in a memo that is in your agenda materials and then I want to turn as

quickly as possible to our panel.

Eric?

DR. MESLIN: Thanks very much and welcome to everyone who could come today.

If you have questions about the report feel free to direct them to me.

One other item I wanted to bring to your attention that I have mentioned before and that is the ongoing work we are engaged in to plan for the third international global summit of national bioethics commissions that will occur in London in September. Work is proceeding a pace on that. There will likely be as many as 40 national commissions in London and NBAC will be represented. I will give you more information on that over e-mail as to places, dates and times but it should be a very productive meeting.

The other item I simply wanted to raise is it gives me pleasure to let commissioners know that a new staff member has joined us. Glen Drew. Glen is here in the room somewhere. I do not see him at this point. He is at the back. I want to welcome Glen from a very distinguished career at FDA. He has joined us on a detail for a period of time to provide support for and direct involvement in our oversight project. He is a lawyer and engineer by training and his particulars and

CV can be made available to commissioners and staff.

So welcome, Glen, and thanks very much for being here.

DR. SHAPIRO: Thank you very much.

Marjorie, a brief report on just an update on the oversight project.

ETHICAL AND POLICY ISSUES

IN THE OVERSIGHT OF HUMAN SUBJECTS

OVERVIEW OF WORK TO DATE

DR. SPEERS: Thank you. Good morning.

The oversight project is progressing nicely as I think you can see from the agenda that we have today and from the materials that are provided in your briefing books. I want to point out that the briefing book you have a description now of the papers that we have commissioned for this report. You can see now who the authors are and a very brief summary of their papers.

We expect that the papers will be done on the dates that we have given the authors or at least very close to those dates. The papers -- the first papers that will be completed are those that are looking at the purpose of a regulatory -- of a regulatory framework and on alternative models.

So it is our anticipation that at the June

meeting we will be able to pick up the topic that we have been discussing around the current regulatory framework and structure and what it might look like that we will be able to pick that topic up then at the June meeting because you will have papers that are ready at that time and we can have testimony also prepared at that time.

The other papers will come in later in June and we will then be able to move forward at the July meeting with discussions around informed consent, risk, vulnerable populations, and then by the fall move on to topics related to the current IRB system and functioning.

I just spend the time to say that to you because I think what it indicates is that this project is on track and we should be able to complete it by the end of this year or early next year based on the way that we have organized the work.

We have also in your briefing book included brief summaries of the ethics codes of a number of social science organizations. We did that for you because in addition to the topic today, which is the definition of research, we want you to become familiar with the types of research and the issues that social science organizations have.

The current regulations for protecting individuals who participate in research covers the full gamut of research, that is both biomedical and behavioral research. It is very easy for us to think about biomedical research because that is often on our minds but the regulations include all research and so our recommendations need to take into account the other types of research.

Carrie Jo Leo on our staff put this section of your briefing packets together and I think she did a very nice job of not only pulling the codes but excerpting the major areas that are related to human subjects protection to give you a flavor of the types of issues that social scientists deal with.

Yesterday Elisa Eisemann and I attended a town meeting in Pittsburgh. This was our second town meeting. It was I thought a very good town meeting that we had. We had about 25 people in attendance and they spoke, I think, very openly and honestly about concerns that they have as IRB members and as researchers. We had a number of physician researchers that were at the meeting yesterday. We will be summarizing the town meeting results and themes for you.

Since this memo was written we have also

spoken with the organizers of the May OPRR-FDA workshop that will be occurring in early May in Orlando and we have the opportunity to do a town meeting on May 3rd in Orlando and wanted to make you aware of that in addition to the one that is going to occur in Chicago in June.

We will also be handing out to you later today a chart that represents the current regulatory system. A number of you have asked me for a chart, a diagram, some representation of the system that we have and so we are going to be handing that out to you at lunch and then talking about it early this afternoon.

DR. SHAPIRO: Thank you.

Any questions?

Tom?

DR. MURRAY: Thank you. One question I had was about the first of the commissioned papers. When I looked over the charge I was not clear whether two possible dimensions were being conflated or whether they would be addressed separately. This is the paper by Donald Chalmers and the two points have to do with regulatory systems versus guidelines or nonregulatory systems. That is the first distinction. The second is between a human subjects protection regime that covers only government funded research and a regime that

covers all research. I just wanted to be sure that they -- both of those dimensions got attention.

DR. SPEERS: Yes. The plan in this -- for this paper is that those topics -- each of those topics be addressed and I would add a their dimension to that, which is comprehension in terms of all research, both biomedical and nonbiomedical research, that these particular -- many of these codes are very general codes that cover social science research, engineering research, as well as the biomedical research.

And to reiterate your point, both federally funded and nonfederally funded research, and some of these systems are regulatory systems but some are not. Some are more principles or guidance that organizations then agree to follow. So it is really those three dimensions that would be addressed.

DR. MURRAY: Will we ask Chalmers also to look at other models for organizing the research ethics committees, not just their -- the rule structure but different ways -- we have talked before about New Zealand's structure which has a majority of lay people on their research ethics committee. Will he be asked to do that or will any of these authors be asked to do that?

DR. SPEERS: Do you want to go?

DR. MESLIN: Well, just to remind commissioners Professor Chalmers is the chair of the Australia National Health Ethics Committee, one of the two national groups that have come out with very comprehensive guidelines for human subjects research, the other being Canada. Chalmers' experience extends to what Tom has described as both local review and national review models. So, yes, we have asked him to address those issues.

In addition, Soren Holme, now at Manchester, formerly in Copenhagen, is being asked that very same question so we will be seeing two or three different papers addressing your points, Tom.

DR. SHAPIRO: Any other questions from commissioners on this?

Okay. Thank you very much. I want to now turn to our panel and remind commissioners that every time we meet we have a different public address system and a different set of rules and so on.

If you want to be heard you press down on the button and a red light goes on like this and when you are finished talking please press again so that it does not interfere with the sound system.

Well, we are very fortunate to have a very distinguished group of people here today to address us

on this panel. I want to thank you both individually and collectively for being here. We look forward very much not only to what you have to say on the matters before us but also through the questions and answers. We hope to have some time here where we can have some back and forth here.

So thank you very much for being here.

I will just go from my left to right here mainly because that is the way it is listed on the agenda and you happen to be seated that way. So I really want to welcome Shirley Fry from the Oak Ridge National Laboratory.

It is really great to have you here and thank you very much for coming. Please?

PANEL I: DEFINITION OF RESEARCH
OCCUPATIONAL STUDIES, HEALTH SERVICE STUDIES
AND POPULATION-BASED SURVEYS

SHIRLEY FRY, MB, B.Ch., M.P.H., CHAIR,
OAK RIDGE ASSOCIATE UNIVERSITIES
OAK RIDGE NATIONAL LABORATORY IRB

DR. FRY: Thank you, Mr. Chairman, and thank you, commissioners.

As you said, my name is Shirley Fry. I am from Oak Ridge Associated Universities, which is a smaller research institute in Oak Ridge just for the

record.

My formal training is in medicine and in epidemiology with a degree in medicine from the Trinity College, Dublin, in Ireland, which is responsible for the alphabet soup, and a master's degree in epidemiology post-graduate at the University of North Carolina.

For more than 20 years my professional experience and interests have been in the study of the acute and long-term effects of exposure to ionizing radiations in humans.

My experience in this field includes the design, performance and scientific direction of epidemiological studies at the local, national and international level among populations ranging in size from less than a hundred up to several hundred thousand individuals who were exposed to radiation accidentally or who were at risk of exposure in the workplace.

I have also served as a member for 20 years, the past five years as the chair, of an institutional review board that has operated since 1971 under a multiple project assurance with the National Institutes of Health. This IRB is responsible for the oversight of human subjects research proposed and conducted by investigators at the two contractor facilities on the

Department of Energy's Oak Ridge site, namely my own institution, Oak Ridge Associated Universities and the Oak Ridge National Laboratory, both in Oak Ridge, Tennessee.

Currently our IRB reviews ten or fewer new protocols a year and inactivates a similar number due to completion. Between 25 and 30 active protocols are reviewed annually for continuing approval, including six currently from other institutions other than our own for which we now provide local site review.

Compared with academic medical and basic biomedical research institutions, our's is a low volume but highly visible and politically sensitive endeavor in the generic sense.

Mr. Chairman, I think you for the opportunity to bring to the commission's attention some issues that currently concern and perplex our IRB. Specifically in the light of recent developments in the scope and nature of federally sponsored occupational health studies or programs involving workers as voluntary subjects or participants at facilities in our IRB's purview. I will ask you to bear with me while I attempt to summarize some background information that I hope may assist you in putting the genesis of these issues into perspective and, therefore, identifying our

evolving concerns.

My remarks are primarily from personal experience but I do not think they are confined to our own experience. I think they are, as I will say later, more generalizable than Oak Ridge.

In Oak Ridge, in our institutions, from the outset in 1950 through the 1970's the human studies conducted by our IRB's sponsoring research institutions was subject initially to institutional biomedical research -- biomedical oversight aimed at protecting research subjects and later continued by IRB review as regulations were developed by NIH and implemented by the institutions.

These earlier studies clearly were clinical research studies involving consenting patients or healthy volunteers or basic biomedical research studies involving, for example, consenting human volunteers or tissue samples.

In the 1980's the Department of Energy's changing mission and directions in biomedical research and a growing concern for the health of former as well as current workers resulted in a decrease in the number of studies at our institutions that unequivocally met the current NIH definition of research and the development at ORAU of record based epidemiological

studies of mortality and to a lesser extent morbidity among DOE contractor employees at multiple facilities nationwide.

In keeping with institutional policy, these studies were submitted to the IRB for determination of the type of review required and in most, if not all, cases the study proposals were reviewed by the IRB and review continued for continuing approval as necessary.

This was and continues to be our policy for epidemiologic and other health related studies whose objectives a priori clearly are to provide generalizable information.

In the 1990's following the transfer of responsibility for occupational research studies from DOE's Office of Energy Research and indirectly to the National Institute for Occupational Safety and Health and the implementation in 1997 of a memorandum of understanding between the Department of Energy and the Centers for Disease Control and Prevention, DOE's occupational health studies were expanded under a congressional mandate to include voluntary medical surveillance programs for selected groups of former workers.

These were programs involving human participants who do not necessarily fit the model of

clinical or biomedical research that is the focus of existing federal regulations and guidance for protection of human subjects and the programs being conducted are for the most part being conducted by off site investigators.

Some of these programs for former workers are now also being offered to current employees as part of their facility's routine occupational health program.

Workers eligible for inclusion in these expanded worker studies or programs are identified from existing plant records either because they are or were employed at a plant of interest, such as gaseous diffusion plant; had a particular job designation, such as a construction worker or reactor operator; or because they were considered to have been or might in the future be at risk of occupational exposure to certain agents such as beryllium.

A number of studies or programs initiated under DOE's expanded health program are identified as medical monitoring or surveillance programs, which by the strict interpretation of the current definition would not qualify as research and thus may be exempted from IRB review.

On closer examination, however, these programs may be found to have the potential not only to benefit

individual participants through referral for diagnosis and treatment or compensation for work related disease but also to generate generalizable information that may benefit the wider and future worker community.

They also have the potential to put individual participants at risk of breach of privacy and confidentiality of their personally identifiable data that are compiled in these programs. This may happen despite the best intentioned and executed protective regulations and safeguards.

Information obtained in developing these programs from existing workplace records and in new face to face interviews, medical examinations and tests, some with genetic implications, in appropriate or the wrong hands can jeopardize individual workers' future employability or economic and social well-being. Thus in today's environment of increasingly sophisticated and potentially intrusive biomedical and computer technologies and heightened public awareness these programs are not without risks, albeit ones that are primarily nonphysical in nature.

Mr. Chairman, I would suggest to you that workers involved as participants in this type of health study constitute a vulnerable population, whether the study be research or medical monitoring or surveillance

by design.

Surely individuals in these populations have as much right to be fully informed of the nonphysical types of risks as has the patient who enrolls in a clinical trial or a healthy adult who agrees to participate in a physiological study to be informed of the risk of adverse physical effects that may be associated with the research procedures.

Only then with this information can workers fully -- make fully informed decisions about their participation in such programs. Under the present system if such programs are deemed not to be research, as currently defined, then the participants are denied the protections of full and appropriate informed consent that IRB review can ensure.

There is, however, a catch-22 here, and that is in identifying or designating a medical monitoring or surveillance program as research so that it may be assured IRB review there is also has the potential to deter the participation of individuals at risk of occupationally induced disease, the very people the program is designed to help, because of an abhorrence or fear of becoming "an experimental subject." I suggest we can do better.

To meet the need for the protection of

participants in the expanded worker health studies at the Oak Ridge site, the IRB responsible for human studies protection in research conducted at OARU and ORNL, our IRB, was designated in 1997 by DOE's Office of Human Subjects Protection Program as the local site IRB.

Included in these studies or programs are current or former employees at four other Oak Ridge site facilities which did not have and previously did not need an institutional review board because they were primarily production facilities. Their operations had no research or other program that involved human participants other than routine occupational health monitoring of current workers by the facilities' medical staff. While the designation as the local site IRB added to our responsibilities and workload, it carried with it no additional resources to meet them, thus taxing the IRB's sponsoring institutions and ORAU in particular.

The issue of additional support recently has been resolved in part for us for DOE sponsored studies. It remains an issue for NIOSH sponsored research studies as well as at DOE's headquarters level where resources are sparse and inadequate for the level of effort needed to ensure protection of human subjects in

the worker health studies as well as the research studies.

Mr. Chairman, members of our IRB, including myself, also have concerns that are evolving policy of applying full weight of IRB review to workers' medical surveillance or monitoring programs is overkill and that we are creating a mountain of bureaucracy out of a mole hill of an issue. Yet to do otherwise would, I think, fall short of doing the right thing even if it goes beyond what is required.

A broader set of criteria which would strengthen inclusion under the umbrella of IRB review without over burdening the system, if that is possible, and delaying needed programs would, I suggest, be helpful for IRB's involved in this gray area of occupational health studies that in the opinion of the majority of our members, including myself lies between unquestionable exemption from and unquestioned requirement for IRB review.

The situation I have described pertains to but is not unique to the Oak Ridge site. Similar worker health studies are proposed or are being conducted by off site noninstitution investigators under DOE or NIOSH sponsorship at 20 or more other active and inactive DOE facilities nationwide.

I have a list of them. There is an overhead just for demonstration. The populations at these 21 facilities represents several tens of thousands of present and former workers.

(Slide.)

Like Oak Ridge, other communities on the Oak Ridge site -- at several of these other sites the worker community comprises a signification portion of the area's resident community. These are company towns and concern about worker health is a concern for the community as a whole. In some cases, negatively impacting its economic stability.

I might add that the issues and concerns I have identified are by no means unique to our IRB in responding to DOE's need and responsibility to protect human subjects in its worker health studies nor I suspect are they unique to DOE as a sponsor. Similar issues and concerns likely pertain to some degree in other industries and institutions in which studies of employee health and other characteristics are sponsored by the company with several pressures on the participants, real or perceived, which that connotes. And where the risk of breach of privacy and confidentiality are personally sensitive information with the potential for harm, each of which beg

protection.

In conclusion, Mr. Chairman, I would hope the commission would take up the issue of the definition of research as a criterion for a participant's right to be protected in health studies or programs as opposed to research studies, particularly as they pertain to workers. Again I thank you for the opportunity to be here today. I look forward to your discussion and welcome any questions you or the other commissioners may have.

DR. SHAPIRO: Well, thank you very much.

Let me suggest to my fellow commissioners if there are any kind of clarifying questions we ask them now if there is issues you want clarified, if not, we will hold our questions until all three panelists have had a chance to present their material.

Any clarifying questions necessary at this time?

Okay. Well, thank you very much. We will return to the questions very shortly. Let me now turn to Dr. John Eisenberg of the Agency for Healthcare Research and Quality. Once again, it is a great pleasure to welcome you here today and we look forward to your remarks.

JOHN M. EISENBERG, M.D., DIRECTOR,

AGENCY FOR HEALTHCARE RESEARCH AND QUALITY

DR. EISENBERG: Thank you. Let me thank you for letting me join you. Before I joined the Agency for Healthcare Research and Quality, I was at the University of Pennsylvania and Georgetown. It is hard to get out of those two institutions without at least paying homage to bioethics and it is nice to come here and have the chance to talk with you about it.

But in this new job I have found new sets of challenges in bioethics and they have to do with several policy questions I would like to lay out to you and ask for some help with but before I do that let me give a very brief introduction for those who do not know much about health services research to this field.

I have a handout, which I have given you in this blue folder, which has an exhibit labeled Exhibit 1, which is a diagram of transition of a continuum of research and what I have tried to demonstrate in this article, which is a sense of what health services research is all about, is that health related research is a continuum, that what we classically define as biomedical research is basic science research moving into clinical trials, that there is in addition to that a set of research which includes cost research, medical effectiveness research, quality and outcomes research,

research that includes synthesis of available information on effectiveness and meta-analyses, and then research on organization, financing and delivery of care.

Conventionally we would call those four boxes health services research. Of course, the boundaries are never quite as bright as we would like for them to be but that is probably a reasonable way to think about this.

Another way to think about health services research is the way that we think about our customers and our themes for the Agency for Healthcare Research and Quality, which is the lead agency in the Federal Government for sponsoring this type of research.

When we think about why we do this research or why it is in the public interest to sponsor this kind of research we think about three sets of decision makers who are trying to make decisions about health care and we are a health care agency.

There are going to be people who are making decisions at a clinical level, maybe they are patients or maybe they are clinicians or maybe it is the two together.

Secondly, there are going to be people who make decisions at a systems level. These may be people

who are purchasers of care working for a large employer. They may be people who are running large organizations, hospitals, integrated systems of care, managed care organizations but they are making decisions about a system and we hope that we can get them information that would help them to make better decisions about that system.

The third are people who make decisions at a public policy level. They may be congressional members or staff but they also may be members of the administration and they also, of course, may be people in states and local governments. Increasingly we are finding members of state and local government legislatures and administrative branches to be interested in this kind of research because of the fact that they have an increasing amount of responsibility for making these kinds of policy decisions in health care.

Those are three customers so what do we try to do for those three customers? We try to get them information in a few categories and one simple way of thinking about is that the three categories are information about the outcomes and the effectiveness of care. Secondly, information about the quality of health care. And, third, information about the cost

and use and access to care.

So if you think about that grid, three customers, three themes, you could pretty much encompass most of what people would consider health services research. The three decision makers, clinical systems and policy, three themes, outcomes and effectiveness, quality and cost use and access.

So I am not going to go into more about health services research although I would love to pull out all my slides and overheads about the field and I would be happy to answer questions but I would rather focus on the intersection between health services research and bioethics in three specific places.

One of them is the ethical implications of health services research; the second has to do with the ethics of health services research; and the third has to do with research on ethics by health services researchers.

So let me elaborate a little bit on each of those and let me also mention that this is a part of the continuum of activity for us as an agency. We had a conference about a year-and-a-half ago on this topic.

There is a book that will be published by Oxford University Press exploring some of these themes

and we have been working with our colleagues at the NIH in the bioethics program there in several collaborative activities to be sure that the continuum does not have a break but that it is, in fact, a continuum.

So, first, let me address this issue of the ethical implications of health services research and maybe -- to do that I want to give you some examples and I want to give you eight examples of research that we have been sponsoring and point out to you, which probably will not take much pointing out, the ethical implications of sponsoring research in these areas.

The first one is that we sponsor a lot of research related outcomes of care and whether we sponsor it or not there is a lot of research going on in this area. Much of it sponsored by the pharmaceutical industry because of the interest in understanding the outcomes of pharmaceuticals.

To measure outcomes we need to measure something, of course, other than whether people live or die and once we move to more qualitative measures of outcomes, quality adjusted life, preferences for various outcomes, people's values for those outcomes, we obviously leave the boundary of nice, neat quantitatively defined entities like whether a person is alive or dead to issues that relate very much to the

value system of the country and recognize that there are cultural differences among different parts of the population and how they would measure those outcomes because their values are different.

Another example: Cost-effectiveness analysis. Our agency sponsors a fair amount of work related to cost-effectiveness analysis, which is, of course, simply a fraction of the cost in the numerator and the effectiveness and the denominator but it raises a number of issues, as all of you know, about the value of a human life, about costing, about what true costs are, about what we do with the information about cost effectiveness in making decisions that some might describe as rationing.

We sponsor work related to the end of life, care of people at the end of life. We sponsor work on racial disparities in health care. Work on something we just were asked to do by the Congress last year, work on bioterrorism and the relationship between the primary care universe, the universe of those providing care in offices of emergency rooms, and the risk of bioterrorism.

Research related informatics and the applications of computers in health care. Research related to patient safety and medical errors, a hot

topic today and one that has been assigned to our agency in large measure.

Finally, technology assessment in coverage questions. We have a collaborative relationship with the Healthcare Financing Administration, which of course has responsibility for making decisions about coverage of services for patients -- for people who have Medicare and they have reorganized their process within the past year so they now have, as you probably know, a Medicare Coverage Advisory Committee, MCAC, which advises the Administrator of HCFA about whether a service ought to be covered.

Where are they going to get the information? Where are they going to get the evidence? They have decided that they will turn to us as a research agency to provide them with the information about whether a service works or not, when it works, but we will not make the decision as an agency about whether it ought to be covered but we will provide the information about what we know, whether it is effective and in what circumstances it is effective.

And so you can see that the leap between the kind of work that we sponsor and bioethical implications is very, very short and we believe that we need help from you and others in thinking about the way

in which a research agency or, let's say to broaden it, a research field ought to deal with the bioethical implications of what might seem on the face some pretty straight forward research.

Just to give you an example of this, the other day I saw a note about what tonight's ER is going to be about. Tonight's ER is going to have several different themes and as I read about each of those themes I realized that we had sponsored research and health services researchers do research that we have not sponsored in every one of these so if you watch ER tonight this is what you are going to see:

You are going to see a little segment on a decision about whether or not to donate an organ, you are going to see a segment about community acquired pneumonia and whether the person who has pneumonia ought to be allowed to die, you are going to see information about end of life care, you are going to see a segment on the care of uninsured children, you are going to see a segment on medical errors and you are going to see something on long-term care. That is at least if the advanced notice of ER tonight is true.

Now you think about those topics and you realize that the national sensitivity to the kinds of issues that health services researchers are dealing

with and the fact that it is very hard to eliminate nor do we want to eliminate the linkages between the kind of research that we are doing and what is on people's minds.

Let me turn to a second topic, which is the ethics of health services research, not so much the ethical implications of what we do but the ethics of doing this kind of research.

I think health services researchers have lagged behind the biomedical research community in addressing the bioethical implications of what we do and how we do it.

I asked for a white paper within our agency about these issues and how we are going to handle them and that is still being worked through but it gave me an opportunity to look at that white paper and tell you what kinds of issues we are facing.

The first one, of course, is informed consent. Do you get informed consent when you do an organizational intervention in one hospital compared to another and whose informed consent do you get? The hospital administrator, the entire medical staff, all the patients in the hospital? When you decide that you are going to change a formulary in one hospital compared to a formulary in another hospital or that you

are going to institute a hospitalist program in one or introduce nurse practitioners in one compared to another.

Well, I do not know who you go to ask for informed consent about that kind of intervention but of course it does put -- it conceptually puts people at risk and the question is how do you deal with that kind of a problem in informed consent.

The issue of large database research is one that is perplexing to all of us. In fact, our agency has asked the Institute of Medicine to look at the capabilities of the current institutional review boards in evaluating research that uses large data sets and they are in the midst of doing that right now. We are expecting a report from them in June.

But what about when you do research on providers? When you are doing research about the way in which health care providers deliver care, do you get informed consent from them and, if so, how do we go about doing so?

The broad issue of confidentiality and large data sets is one that I know that this group has thought about a lot and it is more than just getting institutional review board approval. It is also the way in which that information is handled.

The Census Bureau, as you probably know, has data centers, which are very controlled mechanisms of making data accessible to researchers without -- with limiting the risk of releasing that -- the sensitivity of that information.

We are looking at the model that they are using and the model that the National Center for Health Statistics uses to consider creating some data centers ourselves that would assure us that when the data is being used by researchers it is being used appropriately.

The next issue is one that has to do with the Freedom of Information Act. The -- as all of you probably know, FOIA is now a mechanism by which individuals can ask for information from investigators if that research was federally funded and if it was used to drive a policy made by the Federal Government. And that raises a number of interesting and problematic issues for us as we think about the confidentiality of that information and the way in which that information is made public.

The issue of ownership of research products is not one just for genes but also for tools that are used in health care delivery. Who is it who actually owns the software that we funded to develop a program to

improve the quality of care? Do the people of the United States own that software or the intellectual property or does -- is it available for commercialization?

And then finally an issue that we have and I know that other agencies have this as well, as well as the researchers is the conflict of interest in researchers who are studying not just a drug that they have participated in developing but another kind of a concept that they may have participated in developing. Is it really conceptually different to have a researcher who is evaluating the effectiveness of nurse practitioners when that person is a nurse practitioner or evaluating the role of the hospitalist when that person is a hospitalist than it is to have a person evaluating a drug when that person participated in the development of that pharmaceutical product?

We all have conflicts of interest and we need to think about ways in which we can eliminate or at least control for them.

The third issue that I want to raise -- the first being, of course, the implications of our research and the second being the ethical aspects of conducting the research -- is a topic which I think has been very under funded and under represented in the

research area, and that is funding ethics research.

The funding of people who are researching issues in the ethics of health care delivery. The doctor-patient relationship, professionalism and the quality of care, accountability, resource allocation, the role of markets, patients as consumers, and providers as purveyors. I do not need to tell this group the kinds of interesting research that could be done were there appropriate mechanisms for getting it funded and for supporting that kind of research.

We would like as an agency to be able to support more of this kind of research. So far we have not been able to do so at least as much as I would like to but I think the question for this group, in part, is what should the research agenda be for ethics related research in health care and should there be a mechanism of helping to support that research? Is there a way in which we can cast a wide net among federal agencies and the private sector to support this kind of research?

Let me just finish by saying that as I think about this topic what is research, a lot of the issues that I have already raised come up but one of the most important issues for us is whether or not research is the application of research methods to any reasonable question or whether it is a project whose sole purpose

is the advancement of knowledge for the public good.

At one extreme it is easy to say that something which is federally funded and is intended to be published is research but at the other extreme what if research methods are being used in a quality improvement exercise within a hospital? Is that research? And if it is not research then where is the distinction between something which is federally funded and intended to be published and that kind of internal research based exercise that is used within an organization?

It would be helpful to have some exploration of that continuum and if there is a fine line, let's draw it, but if there is not a fine line, which I suspect there is not, then we need to think about where if there is going to be a regulatory approach to this kind of research where the regulation starts and where it stops and where guidance starts and when it stops.

I would be happy to answer any questions or clarifying points.

DR. SHAPIRO: Thank you very much.

Again, if there are any clarifying questions we will take them now. If not, we will wait a few moments and take all our questions for the panelists at the same time.

Thank you.

Let me now turn to Professor Bradburn now at the National Science Foundation, a very distinguished scholar as many of you know. I think he may be talking to us about yet another aspect of using information and so on with respect to various populations and large groups.

Norman, welcome. It is very good to have you here.

NORMAN M. BRADBURN, Ph.D., ASSISTANT DIRECTOR FOR SOCIAL, BEHAVIORAL AND ECONOMIC SCIENCES, NATIONAL SCIENCE FOUNDATION

DR. BRADBURN: Thank you very much.

I have some transparencies and somebody is going to do them for me.

I think what I will be talking about is a nice progression from what has been said and just kind of carries on from what it is.

(Slide.)

I guess I should say since I have just come to NSF from the University of Chicago and the National Opinion Research Center, I should do the standard. I think this is not official NSF policy since one of my colleagues is here so maybe she will keep me honest but I have spent many years in methodological research and

survey research so I am really drawing on that experience rather than anything at NSF.

If you could do the next transparency.

(Slide.)

Obviously in the short time I cannot go into great detail about what all the subtleties of what is research and so forth but I take as a quick definition from the survey population based things that it is the systematic collection of data to answer a general question and the kind of data that we deal with can be and mostly is respondent's answers to questions in an interview situation but it can also be behavioral observations. It can be records and it can be biological specimens or some combination of these kinds of things. We do surveys in which we do get -- population based surveys in which we do get biological specimens.

(Slide.)

The important thing I think -- or an important thing to keep in mind about population based research is that it is about groups and not about individuals. That is the data are used to make statements about central tendencies, variances, covariation based on aggregating data but the data are obtained from individuals for the most part but the object of it is

to make some general statements and not statements about individuals. This is perhaps the major distinction between this and clinical research or research that may benefit or harm in the case of individuals.

(Slide.)

Just to go you through the quick steps of surveys. Survey research involves, first, defining a population that is to be studied, drawing samples from the populations, collecting data from the sample, preparing the data for statistical analysis and doing the analysis, and I suppose I should add writing it up.

Each of these steps has some potentiality or at least implications for kind of ethical considerations and that is what I really wanted to spend the rest of the time on.

(Slide.)

There are two -- as I see it, two main ethical concerns in surveys. There is privacy and confidentiality. I take the distinction here that was made by the Privacy Study Commission in the '70s between privacy and confidentiality. I think it is very important to keep these two concepts separately.

Information privacy is defined by the

individuals' right to control the use of information about themselves as opposed to confidentiality, which has to do with the sharing of data only with those for whom disclosure has been consented to. So you have the privacy issue which is involved in consent and you have the confidentiality issue which has to do with what happens to the data sort of after it has been collected or after the consent has been given.

(Slide.)

First, let me talk about issues related to privacy. There are three big issues related to privacy as I see them. One is who gives the permission. How is the permission given? And how often does the permission need to be given as an issue. I would say just, in general, that in the surveys --

(Slide.)

-- the issue often is not so much informed consent as what I say is informed refusal since in most surveys refusal is given before they even know what it is about so that our problem often is to try to keep the attention of a potential respondent long enough to explain to them what it is that we want them to do.

Now I will -- because the time is very short I am going to make some fairly perhaps bold assertions which we can talk about later and I would so warn you

that these perhaps are a bit different from some of the at least evolving practice but in this -- at least particularly the way IRB's have been moving.

But generally in terms of who gives permission I would maintain that competent adults give permission for themselves in surveys and the caretakers give permission for children or noncompetent adults and we can explain that later on.

(Slide.)

In terms of how permission is given I would argue that written permission is not ordinarily required in surveys because in most situations it is a -- you are approaching people either in their homes, over the telephone or sending them letters. They have ample opportunity by their behavior to refuse so in the survey world it is behavioral refusals more than question of written permission.

The written permission, however, is needed for access -- what I call here is access from third parties but frequently we ask for access to records to go to consult medical records, to consult other kinds of records, which we blend with the data from the individuals. Obviously in those situations written permission is needed.

And I -- the most controversial -- one of the

more controversial issues right now has to do with permission -- parental permission for surveys involving children and the question of whether it is active or so-called active or passive permission, that is passive permission is when the school essentially says this is going to happen unless you object -- unless you do not want your child to participate it will happen. Active permission is saying, no, you have got to written permission before the child can participate.

We can get into this. I would sort of argue for most studies involving children for which there is no sensitivity or risk really to the child that passive permission is sufficient although the trend has been going in the opposite direction.

(Slide.)

How often is permission given? This is another growing kind of issue because of rediffusion or other uses of data. I would argue that permission needs to -- certainly needs to be obtained at the beginning of a study, that is either active or passive but that ordinarily permission does not need to be obtained again unless there is a major change in the conditions described at the time of the original permission and this is a very difficult issue in practice and, in principle, it seems to me it is fairly

simple and straightforward but in practice what constitutes changing the conditions is something that is argued.

Okay. If we can now turn to issues related to confidentiality.

(Slide.)

There are three issues that I see as primarily of concern with regard to confidentiality. That is who has access to the data, what are the threats to confidentiality, and what are the techniques for protecting confidentiality?

(Slide.)

Who has access to the data? Well, the research team is clearly the major group that has access to the data and I would argue that research teams have to be carefully defined, that is who is a member of the team, and you have to have essentially signed confidentiality agreements that the people who are involved in the research will maintain confidentiality of the data.

And that -- more than the signed actually, I think this is a case where you are training -- you have got to be vigilant all the time to make people who are involved in research understand the importance of confidentiality. This is not something that you can do

on a one time kind of basis. It is something that has got to be embodied in the research organizations.

Secondly, data cannot be refused -- rediffused or linked with other data -- I mean, they can be I would argue under special conditions and I will talk a little bit later about what some of those conditions are.

Secondly, is if there are public use files as there frequently are from large datasets they must be constructed in ways to protect confidentiality, and again I will talk in a minute about some of those techniques.

(Slide.)

What are the major threats to confidentiality? I think the major threats to confidentiality are basically overlooked by most IRB's because most IRB's as far as I can see are concerned with what I would call inadvertent disclosure or disclosure in the process of things but, in fact, I think the real threats are in much more difficult areas.

Law enforcement, we do not -- except for those -- for data collected under Public Health Law 408 -- I have forgotten the section now -- are not -- do not have legal protection so consequently they can be subpoenaed and there are some techniques that we use to

thwart that.

One I worry a lot about increasingly are private suits or class action suits, particularly as in the medical area one has seen this, the University of Chicago has been -- I hate to say a leader in this, we have been sued for the DES -- the studies that we did a long time ago.

FOIA Dr. Eisenberg just mentioned that as the new regulations, which though they did get modified with regard to making data available that used to be protected in the sense that from FOIA at least, that is -- that is data collected under grants are now available under FOIA although there are -- the regulations did get changed to protect it somewhat.

An increasing problem is ID theft in which records -- individual identifiers and so forth are lifted essentially or stolen.

And computer list matching, hackers I put on this, that there is just an incredible new set of problems because of what can be done with computer matching. Even when you think you have files that have been sanitized for confidential information. Because it is possible to link with other lists it is possible to recover data in ways that we had seen before.

And inadvertent disclosure, which I think is

probably the least problematic because it is something which can -- I mean, it does happen every once in a while but can be -- you know, if you train people.

(Slide.)

There are two techniques for protecting confidentiality that I want to talk about. One is restricting users, restricting access to the data, and the other is altering the data. Okay.

(Slide.)

In restriction of use there is the strong form and the weak form. The strong form is the one that Dr. Eisenberg just referred to and that is data enclaves which the Census Bureau has been doing and NCHS is beginning to talk about.

The weak form is licensing which the National Center for Educational Statistics has been a pioneer, and that is making individual microdata available to individuals -- to researchers with a rather elaborate protection system in which they fill out forms and swear and so forth, and are subject to the same kind of penalties that the research -- this is really extending the breadth of what the research team is.

(Slide.)

Newer techniques which are -- I do not know whether Dr. Abowd may talk about these this afternoon -

- I mean, this morning, later in the section, the next section because economists have been -- and statisticians have been pioneering in these.

The strong form of this is using sort of modern -- multiple imputation or perturbation techniques from statistics to recreate the data structure but with data that is synthetic. Now this is -- requires understanding the structure of the data and is very model dependent but it allows for essentially construction of synthetic datasets which are confidential because they are not the real data but they have the properties of the real data for analytic purposes.

The weak form which is what is mostly used is -- ranges from top coding, which is collapsing categories so that when the -- or other kinds of collapsing categories to insure that there is a minimum size for analytic purposes, and the Census Bureau does this and it is public use tapes and most of the statistical agencies do this in their public use tapes.

A third one, which is not one that NOSC has used a lot and is not so widely known in the medical area, I think, but one which I think helps in many kind of areas where you want to link particularly medical records with data from individuals on preferences and

values, some of the kinds of research that Dr. Eisenberg was talking about.

This is having the -- taking the identifiable data and keeping it on a third file. Typically in our cases we have kept these in Canada where they are not subjected to subpoena.

And you have one -- you have a file which is the original data file stripped of the confidentiality but has an identifier on it, unique identifier. You have the data file which has the unique identifier but if you want to do follow-up data or you want to do other kind of mergings of it you have to go to the third party that does the linking and so nobody has all of the data but you have to go through different people to do it, which means there is a lot of protection and a lot of confidentiality protection that you cannot get -- and also you can -- although this has not been tested in the courts, as I say we do keep this out of the country, which helps on kind of the subpoena side. And that is not a trivial problem.

Okay. My conclusions -- the one thing I do stress with all my fellow researchers and so forth is do not promise more confidentiality than you can deliver which I think many researchers do not understand that there are limits to what --

particularly if they do not have the legal limits that sometimes they think they do.

A second point, I think, which I hope you will discuss is that the benefits of research need to be taken into consideration as well as the concerns for privacy and risk to confidentiality.

We are not very good at quantifying the probabilities relative to -- you can say theoretically -- you know, we can identify all these sort of things that might happen but they are -- for the most part, very low probability events and if you -- as I am afraid many -- the trend is to say, well, if you go to a zero risk type sort of situation -- well, if it is a zero risk situation we will have to stop doing research because there is not that.

So my final plea is that being too risk averse may prevent valuable research from being done and I think that is where we are.

Thank you.

DISCUSSION WITH COMMISSIONERS

DR. SHAPIRO: Well, thank you very much. It is really very helpful.

I want to thank all panelists and turn to commission members to see -- any questions for any of the panelists now is fine.

Bernie?

DR. LO: Dr. Bradburn, on your next to last slide, could you explain to me what top coding is and how it differs from collapsing categories?

DR. BRADBURN: Yes. The simplest sort of thing is that if you are getting exact income, for example, there are very few people who have very high incomes and you just collapse to $100,000 or above or something like that, so that the people who will be unique kind of cases, or anything like that, which -- essentially it is pulling in the tails of a distribution.

DR. SHAPIRO: Marjorie?

DR. SPEERS: I wanted to just make two clarifying comments for the commissioners.

The first is that when Dr. Eisenberg and Dr. Bradburn spoke about FOIA, what they are speaking about is what is referred as to OMB Circular A110 and we will get a copy of that legislation or regulation for you to look at.

And the second point I wanted to make is that we are currently discussing having another commissioned paper on privacy and confidentiality issues. You have raised this before and we have taken it seriously and we are having discussions now because the whole topic

of confidentiality, I think, is one that this commission will want to look at particularly as it is evaluating risks associated with research.

DR. SHAPIRO: Thank you.

Jim?

DR. CHILDRESS: Thank you, all three panelists. I found your perspectives very helpful.

Let me address this question to Dr. Fry. In the medical surveillance and monitoring of workers, you indicated that the IRB system is not the ideal place but given our current situation it appears to be the best place at least from your standpoint where we could address some of these issues. And I have got a couple of questions.

I guess one would be what else would be needed elsewhere in the system in order to obviate the need for IRB review? What kinds of protections would be needed elsewhere? I am sure some of them have to do with the issue of privacy and confidentiality.

But, second, since you suggest that medical surveillance and monitoring workers can be brought under IRB review and perhaps should be in our current setting brought under IRB review because of risk, especially breaches of privacy and confidentiality, and because of the possibility that this may advance

general knowledge, I guess on your -- given that, I guess I would be interested in your saying a bit more about your -- the paragraph next to the last page where you say, "A broader set of criteria which would warrant inclusion under the umbrella of IRB review without over burdening the system would be helpful for IRB's involved in this."

I guess I would be interested in your saying more about that broader set of criteria and then what that would actually involve for IRB review and guidance since you want to fall between the unquestionable exemption and the unquestioned requirement for review, but something in between. I would just like for you to elaborate a bit if you would.

DR. FRY: Thank you for your question. Nothing trivial.

Well, in answer to your first question what would I like to see as an alternative to IRB review, I think something less demanding than IRB review but a clear set of guidelines as to what is needed to protect subjects in that situation as opposed to research that could be referred to and could be given to medical department directors, medical occupational health physicians that are conducting those types of studies or programs.

And I think that applies to each of the other topics you referred to. It is -- I really have not got anything specific in mind but certainly something clear, written down in the way of guidelines rather than IRB's or investigators or medical directors making up what they think is acceptable or needed.

DR. CHILDRESS: And would these mainly concern privacy and confidentiality or do you have other matters of concern that you would like to address?

DR. FRY: Well, it is primarily in the occupational setting I think it is very important for privacy and confidentiality, particularly as new techniques, new technologies, both in the biomedical area and in computer sciences, can put people's employability at risk in the future if they become identified as having a risk for some disease or having been exposed to a certain agent although the data are not intended and one would hope would not be released but that they could get into the wrong hands and be used against individuals.

We have had experiences of that in our own community in the area of beryllium where now we have beryllium workers who are eligible to be tested for sensitivity to beryllium but they are very wary of being tested lest they test positive and that affect

their employability and then beyond that even their economic and other factors such as being able to get health insurance or mortgages or other factors that are linked to employability.

DR. SHAPIRO: Thank you.

Diane?

DR. SCOTT-JONES: I have a question for actually all the panelists about how you see research developing in the future in terms of the separateness of different kinds of research. We have asked you to come to speak to us about different kinds of research in which you have been involved but I am wondering if you see these boundaries as really firm boundaries.

I would like to give you an example of what led to my question. One of the major studies in my field that is going on now is the National Child Care Study and it began as a psychological study but now that the children being followed longitudinally are approaching adolescents they are beginning to add some studies of hormonal changes so it is becoming more than just a psychological study.

I am wondering how you see research developing in the future. Will it be more research that is broader and encompassing different kinds of research as opposed to research that can be neatly fit into a

category or kind of research?

DR. SHAPIRO: John?

DR. EISENBERG: The reason that I presented the continuum is to make the case that there are no clear demarcations. I think it is easy to tell one extreme from the other type of research. It is easy to tell survey research from a clinical trial. But there are overlaps and much research, I think, in the future will be multi-disciplinary in which case we are going to probably have a single project with multiple kinds of interventions and multiple ethical dilemmas.

So my suspicion is that what we are -- my suspicion is we are going to head in the direction of more fuzzy boundaries rather than more clearly demarcated boundaries and it seems that the challenge, therefore, is to have some general principles that would apply across the different kinds of research recognizing that the implementation may be different for different kinds of research but the general principles are going to be needed.

DR. SHAPIRO: Norman?

DR. BRADBURN: I would go a little bit further, I think. I do not think there is any difference in research. I mean, except in a couple of lines. Experimental or surveys.

The other has to do with what -- you know, how you define your population and how you define whether you are doing a total census or whether you are doing a sample.

So there are a few sort of basic kind of designs but the other thing, you know in surveys you can -- whether they are population based or whether they are clinically based, you can use all kinds of different kind of data. There is personal responses, biological specimens, records.

One of the more difficult issues, I think, is when something starts out not to be research and then becomes research. That is -- and this is something for lots of reasons many of us like to do: You have a record system which is collected for administrative purposes or for some -- let's just call it administrative purposes. And then later on you want to -- you say ah-ha here is a record of data -- I mean, of behavior or things that people have done in some system using Medicare records or other kinds of things and you say, oh, well, we could answer some general questions by looking at, you know, reorganizing these files in ways and putting questions to them. And then this is the problem I alluded to in say the conditions change.

You entered a system either because you were

required to because you are getting some benefit and then somebody wants to do research on it. And that seems to me a difficult -- at least it is an issue where there is a lot of discussion about how you handle problems like that.

So I do not think there is -- in principle, I do not think there is really --

DR. SHAPIRO: In an interesting way that particular problem has an analogous implication for the tissue study we did which was a bank of tissue samples which was collected for one purpose and now should be used or perhaps could be used and what conditions would apply and it is a little different in some of the areas you talked about but it is similar in principle.

Yes, Dr. Fry?

DR. FRY: That situation is particularly pertinent to occupational studies where you generally start out with data that are collected for entirely different purposes and in these particular health studies going on now as opposed to health research there is a very fine boundary, as I referred to, that while they are advertised or entitled monitoring programs and surveillance which would be to the benefit of the individual there is that very fine line at some stage somebody is going to put those data together and

make them generalizable and we have -- we have had experiences with that and we have to -- that is one reason why we felt we had to have IRB review in addition to the privacy was that we need to be able to monitor those studies to find out when that line is about to be crossed.

DR. SHAPIRO: Thank you.

Alta

MS. CHARO: Well, I suppose this question is actually for all three of you because you have great experience in working with IRB's in your respective areas.

We have heard a number of people suggest that the system which currently does not distinguish among levels of risk or types of research at the outset but instead has all forms of research stored in the same place and then get handled somewhat differently depending on how the administrator and the IRB members view it is a system that is burdensome because it catches too much research and forces it into the IRB review process.

Or some people have said the actual form of review is inappropriate for certain kinds of research, a comment that has frequently been made particularly with regard to behavioral research and survey research.

I would like to ask you to comment on what kind of system you think would work best in your respective areas achieving needed protections while avoiding what, Dr. Fry, you had said might be excessively burdensome regulation without stifling needed research as it has been said by others.

And let me -- and I apologize for going on a bit but let me give you just a couple of the kinds of example that I have seen come up before our IRB's. We have seen proposals for research that is as benign as -- well, let's see in the nursing field there is a move towards a lot of Heidigarean and Hermeneutical analysis, which involves lengthy discussions with patients about their experiences and trying to draw lessons from that.

We have also seen purely survey research that asks women about their alcohol use over a period of time but it is actually being done in conjunction with cost-effectiveness evaluations and outcomes measures because it is part of a program to try to reduce alcohol use during pregnancy and it is in a place where there have been special education programs aimed at pregnant woman frequently taking place on Native American Reservations where cell size can be a problem

because there are very small numbers of people who are giving birth at any particular time.

Surveys of school children on attitudes and behaviors, none of which are illegal but which might engender some disapproval by their parents.

Would this kind of range and with this interaction with some biomedical concerns in the case of pregnancy and such in mind, how would you begin to think about an appropriate structure for a system that does or does not distinguish among areas and levels of risk at the outset?

DR. SHAPIRO: Norman?

DR. BRADBURN: Those are obviously very difficult questions.

The -- let me make two comments. One is I think, in general, I would see that at least from the example that you have given that -- comparing with practice -- that we ought to give much more attention to confidentiality. The protection of confidentiality issues than typically, it seems to me, IRB's do, who on the whole in my experience are more concerned with what they view as privacy issues, which in the survey world I guess has been more, you know, like would people be offended by asking these questions, would they -- you know, would it be upsetting to them so all of which are

kind of speculative in a way and there is tremendous individual variance. But -- and we know people do.

But it seems to me the real issues are as you take the Indian Reservation one and so forth, how do you protect the confidentiality of those data so that you can use them with -- and that is -- you know, those are the kinds of things which I think really are important to protecting the individual, not so much whether you -- you know, you get a signed -- I have a feeling that people somehow or other think that getting people to sign a consent form and so doing takes them off the hook or answers the problem but that is not to my mind where the real issue.

The real issue is what your procedures are and your understanding of the issues after you got the data and you can get so much on the other side that you end up not getting any data because you somehow or other send people -- I mean, in the survey world the parties say why sign a compendium when all I have to do is, say, you know, hang up the phone or not let you in my house or say go away when I do not understand necessarily even what it is.

I always say that the only way you can get informed consent is after you have done the interview. Then you say, all right, now that you know what it is

all about do you consent to allow your data to be used. In the medical world you cannot, I guess, do that. Consent to the operation and then say I did not like the operation now do it backwards.

But I think confidentiality are the real sort of issues.

What is bothersome to me is that -- and the trend that I see in IRB's -- is that they are becoming more and more conservative, that is there is a kind of network at least in the ones that -- there is a kind of -- I do ont know what you call it -- ListServ kind of network that administrators of IRB's communicate with one another and they sort of say here is a new problem, how do you handle that, and then everybody sort of responds.

And what happens is the most conservative view wins out because people see, oh, gee, they interpret it that way so maybe we better do it too. So over time I have seen things getting more and more restrictive and that is partly, I think -- or no, I would say more than partly. Largely, I think, because there seems to be only one remedy, that is you close down the entire institution, and I have seen certainly, and I am sure others at our university, a marked change in the way IRB's have behaved since, you know, Duke and other

places -- you know, most recently in Chicago, the University of Chicago, Illinois in Chicago, gets closed down.

And it is easy to say for the NIH -- or says, you know, well, you know, those are -- you know, we warned them and so on and so it is not that it just comes out of the blue but -- and that probably is true. But still the protection -- the tendency to protect the institution has become so strong because of these things that now things that people used to think were not problems, they have always said, no, no, you have got to do this, you have got to do that.

And multiple times. I mean, getting -- you are using a public data file, the organization distributed it has already sanitized the file. They have already gone through their IRB's and so on and so forth.

Now here is a graduate student from another institution who wants to use the public file and has to go through the local IRB to get it and it was not -- I mean, in a case that I saw, which kind of got me interested in this, it was not even a case of -- I mean, something that you would think would be expedited.

I think -- I mean, I am -- I think everything

should be reviewed. I mean, I -- because I do not think you should have -- otherwise people will play games about how you are doing things and I think it is irresponsible to say here is a set of standards which have to be sort of done and then exempted either because of the sponsor or because of something else, exempt them but you cannot do that unless it is clear that a lot of things either get minimal review or expedited review or do not -- or sort of blanket-ly reviewed, which when -- for years it was not -- that is the way it was. I just think in the last four or five years it has become much more burdensome and much tighter and this is a kind of bureaucratic creep.

DR. SHAPIRO: John?

DR. EISENBERG: I am not sure I agree that everything should be reviewed. As I think about my own proposals to IRB's and the IRB's with whom I have worked, much of health services research is either expedited or exempted, and that has been of great relief to me when that has happened, I must say, but I have never understood how they decided to expedite or to exempt my research as opposed to requiring a full review. It seemed almost capricious at times and dependent upon who the administrator or the chair of the IRB was.

It strikes me that they cannot ask every investigator and they cannot ask every -- and we cannot ask every IRB member to review a full explication in every proposal of every potential ethical implication. We can, of course, ask how they are going to keep the data confidential and a few other specifics.

It seems to me the question is not so much whether we review every proposal as whether there are standard guidance -- guidelines, rules of the road for researchers who want to know how they can conduct research in an ethically acceptable manner.

Let me raise an issue that is not related to the data but is related to the relationship with the funding agency. I used to do a fair amount of work sponsored by the pharmaceutical industry and because there was no standard for the relationship between the investigator and people who did economic research with the pharmaceutical industry we wrote a standard contract. It turned out that nobody else had done this so we published it. Of course, you know, being in academia we published anything we could.

But it was a very interesting exercise that while there was great attention to confidentiality, there was almost no attention to the relationship between the funding organization and the researcher.

And we could go down a list of other implications and other aspects of research that I think are very serious and need attention, and which we just basically in most instances put on the researcher, many of whom are junior, and say tell us how you are going to handle this in an acceptable way with very little guidance.

And as I look through these summaries that you have of some professional organizations I was both impressed and depressed. I was impressed that you found so many that had some guidance. When I looked in the epidemiology and health services area for organizations who provided guidance to researchers about how to handle data in a confidential manner, I could find two. Two organizations that gave guidance other than keep it confidential.

So I am impressed that there are so many of these but as I look at them I realize how much of the guidance here is very global and conceptual and not operational.

So it seems to me that if we are going to really help the researcher and even more importantly help the subjects that going through 7,000 odd -- is that how many IRB's there are? -- and expecting each of them to reinvent the wheel and every investigator to reinvent the wheel without some national guidance about

how to conduct research in a manner that is going to preserve the rights and prerogatives and confidentiality of the individual subject is totally unrealistic.

DR. SHAPIRO: Arturo?

Oh, I am sorry, Dr. Fry.

DR. FRY: I would just like to comment on the privacy and confidentiality in federally sponsored research is that we feel it is very important that the subjects, whether it researcher or participants and other types of programs, understand that the privacy and confidentiality can only be protected as far as the law allows, and this is a great misunderstanding that a lot of people in our field and in the medical patients in general do not understand that the limits of the protection of privacy and confidentiality.

I think we heard at a recent talk that there are 17 avenues that data can be released without any identifiers and without any constraints on it just through the normal system of data going here, there and everywhere for various reasons.

So I think it is important that people understand that upfront when they are considering participating in a -- it should not be a deterrent but they should be quite clear -- it should be quite clear

to them that there is no -- we cannot guarantee privacy or confidentiality. We can try but --

DR. SHAPIRO: Norman?

DR. BRADBURN: I just want to clarify I do not disagree with Dr. Eisenberg. When I said I thought everything should be reviewed I meant there should not be -- it should not -- you do not have to review things because it is government sponsored but if it is privately sponsored you do not.

I totally agree that you should have these different levels so I think it is -- you know, and better guidelines. I think if the IRB's had more consistent guidelines.

DR. SHAPIRO: Thank you.

Arturo?

DR. BRITO: This question was partially dealt with a little bit earlier but I want to take it from a different angle and it relates to the definition you had up there, Dr. Bradburn, of what research is.

And what concerns me is that the systematic collection of data is often done by the clinician or the researcher. In his or her mind it is not necessarily with the intent to do research. We often talk about therapeutic misconception and we often refer to it from the point of view of the patient or subject

where they believe that the clinician is actually providing therapy for them even though it is research.

But I think sometimes we have to think about it from the clinician's point of view. When a clinician does a survey, himself or herself, they sometimes have therapeutic misconceptions because they feel that that collection of data is going to somehow help that patient. It may actually be harming the patient or may actually do absolutely nothing for the patient.

And so my question with the definition is at what point aside from the systematic collection of data do you have to include in there that there is going to be intent to do data analysis or is that a necessary addition to that definition that the intent from the onset is going to be that there is going to be data analysis but sometimes you have the collection of data and we -- and it was spoken about before that the -- after the fact then someone says, oh, well, this is good collection -- you know, this is good data, let's go back and look at it.

So where does the definition start and end, I guess, is what I am asking?

DR. BRADBURN: Well, it is very hard, you

know, at the margins to make the distinction. The distinction -- the basic distinction I would make is whether the -- what you are going to do with whatever information you collect is to make some decision about an individual's fate in some kind of way or you are going to say something general about a group of people.

That is -- if you -- research in my mind is saying something on average or in general or something like that and it is not making anything -- it is not going to be used to make an individual determination about the individuals.

That is why confidentiality in these areas becomes such a critical area because, as Dr. Fry mentioned, in many kinds of research if the data about that individual, which the researcher is not really concerned about the fate of the individual, but if that became known to some other people who are concerned about the fate of the individual, like an insurance company or an employer or something like that, then it is not used for research purposes, it is used for individual determination purposes, and that is the critical distinction in my mind.

DR. BRITO: But sometimes with data collection without data analysis there are conclusions drawn about groups so is that --

DR. BRADBURN: That is bad research.

DR. BRITO: That is bad research. It is still research.

DR. BRADBURN: Research can be good or bad, too.

DR. BRITO: Right.

DR. BRADBURN: I mean, obviously at some level every physician who treats a lot of patients is accumulating a sense of what you do for these kinds of patients, you know, maybe not very systematically or something like that.

DR. SHAPIRO: Thank you.

Larry?

DR. MIIKE: I have been practicing my technique of asking multiple questions so if you have been to our past --

(Laughter.

DR. MIIKE: I have just sort of a comment on Dr. Eisenberg and then my question is for all of you but particularly for Ms. Fry.

I think the reason why most of your research is either exempt or expedited is that it is minimal risk and it involves data sets and the regulations are quite clear about what are exempt and what are expedited review. It is just that it seems like a lot

of IRB's do not understand that.

And then the other one is that in terms of group consent I think the current regulations also addressed that in the section about waiver of consent and I think that particularly the issue about whether it is practicable to obtain a consent. If you do not know who to ask it is kind of impracticable to be able to get there so I think that within the current system they might be able to address that.

My question is later on this afternoon we are going to have a discussion about what is currently under expanding the definition of research but from my point of view it is really not expanding the definition but including for review the kinds of activities that you are talking about that may not be strictly research.

Ms. Fry, what is holding back your agency and your IRB's of reviewing organized activities, research or not, that raise the same kinds of ethical issues that research projects raise such as surveillance studies by something like the IRB but not having to be slavishly following the IRB regs? Why can't they do an ethical review of those kinds of projects because it needs a review?

DR. FRY: That would be a possible solution.

The problem that we have or the agency has is that the occupational physicians, occupational medicine people, who are doing current worker health programs in the facilities and are now doing some of these formers, we also have these former worker studies, they see that as medical surveillance and a medical program as opposed to research.

But we come to the difficulty is where the IRB sees the ethical problems in that program primarily because of the privacy and confidentiality issues.

DR. MIIKE: Then wouldn't it be -- then it is more a question of educating your surveillance physicians to say that, look, in the work that you do there are these issues that arise and that there really should be someone outside of the project to assure that these kinds of things are being addressed.

It seems to me that is the issue, not so much -- and rather than getting strapped to whether this is research or not and whether the IRB has a purview over the activity.

DR. FRY: Well, we have taken the tact and I think several of the other IRB's that have similar questions that they will just take the programs and review them for -- essentially for the ethical issues. That is the big point about them. Are the ethical

issues and are these people being fully informed and being protected?

These are voluntary programs. They do not have to participate in them. Participation may be and hopefully is advantageous to them but they need to be able to make that decision with full information about what it is they are getting involved in and what may happen to their -- what will happen to their data.

Thank you.

DR. SHAPIRO: Bernie?

DR. LO: I first want to thank all three of the panelists for some very, very useful presentations and discussion.

Perhaps just parenthetically ask Dr. Bradburn if you could make available the slides.

As I listened to your presentations and discussions I have become more concerned about a dilemma I think you are sketching out for us. That you very nicely have sort of shown us that research constitutes a spectrum and there are things which maybe are not really research but have enough of the characteristics of research, namely risks to individuals where the benefit does not necessarily go all to them, that we ought to give it some oversight.

And the current system, as you all know, is a

very dichotomous one despite the continuum. We say that if it is federally funded it falls to the IRB, if it does not -- outside, an MPA does not have to -- and you have all been calling for some oversight of things that right now are falling through the cracks. They are not given any oversight at all.

But you have also warned us about the dangers of overkill, I think one of you said, or stifling research. And it seems to me that you have been suggesting that eventually we need a much more flexible system where some things go through very close scrutiny and other things just -- we just need to make sure that the investigator or the person doing the project follows the rules of the road for ethical conduct of a project.

But I am not sure we have those rules now and I am not sure we know what the full array of kind of techniques for review there are other than what we currently deal with.

So I am trying to think of this transitional state between a very, very serious problem we have now where things are not being overseen at all, which present real risks to the patients.

Versus a system that is flexible enough and provides enough explicit guidance so that most

researchers or most -- I do not know what the term should be -- project leaders can say, look, I know this is going to be ethically done because I followed the fairly specific guidance that has been given by a whole bunch of organizations and all the IRB needs to do or the IRB-like bodies is just check off that I have fulfilled the requirements. You know, they do not have to sit on it for two months.

What do we do trying to get there? I mean, how do we sort of say let's do something but let's not too much and let's try and really push ourselves towards a system that down the road some time will be flexible and yet provide protection?

DR. EISENBERG: Well, Bernie, I think you have clearly articulated what I was trying to say, which is that we have a system of oversight and regulation to be sure that people are following the rules of the road when the rules of the road do not exist.

At least that is what I am hearing you say and it is what I was trying to articulate as well, is that if we cannot provide better guidance or better information to people about the behavior that is acceptable then it is hard to decide what the regulatory or oversight mechanism ought to be to be sure they do ranging from voluntary participation to

requiring approval before they could begin their project.

It seems to me that all of this really boils down to independent of how it is funded and independent of where it is being conducted, independent of whether it is going to be published, is whether the individual subject is at risk, and if the individual subject is at risk then it ought -- then there ought to be some rules of the road about how the intervention ought to be conducted.

Whether they are at risk because they might have harm done to them because of the intervention itself or because of some downstream harm that is done because of the dissemination of the information that is obtained but the first problem is that it is hard to find. If it exists it is hard to find and I do not think in most cases it does exist. It is hard to find the guidance in those rules of the road.

DR. SHAPIRO: If I could just say a word about that, Bernie. As I listen to this and as I think about this issue the two of you have just been talking about, there is almost an infinite number of cases, each one of which has its own special characteristics, and it seems to me that we would need to aspire to over time something that is analogous to common law cases.

There is just going to have to be a developing -- we can start somewhere and that is the point being made is well taken that we have to do better than we are now in starting somewhere and giving better guidance, I think, is a very good point. But in the end we are going to have to assume that somehow or provide somehow for the fact that as sort of common law tradition arises case -- through case law or cases and so on that are more publicly available, and there is a case right now that will enable, you know, guidelines to be improved and supplemented and modified and so on and so forth as we learn more because these cases are so various and new ones come up all the time.

Yes, Norman?

DR. BRADBURN: I think that the -- I quite agree with that and part of the problem is that the way it -- IRB's were set up kind of in a way was to give a lot of local control and not have -- try to formulate regulations and so forth.

But I do -- I mean, now that there has been more experience and so forth, and I think one of the things that IRB's -- in the regulations they are supposed (A) to have experts on particular methodology and a lot of the problems have come where IRB's -- because there are new blends of methodologies and so

forth you get people who are not trained in one area trying to assess what the risks are in another kind of methodology. So there is that problem.

There is very little training of IRB's as far as -- I mean, the people I know who can get on IRB's, they just kind of -- they get there and they learn by doing, and so there is an enormous amount of variance and, as I said, I think the current trend is to go -- to be risk averse.

So I think you need kind of training, you need better guidelines, we need to -- we could do with some research on IRB's. I mean, some of these areas -- you know, it is not that you cannot -- it might be hard but it is not impossible to do -- to research in the area and I do not know that there is much research being done.

DR. SHAPIRO: We have come to that moment where I am getting to be conscious of the time and the time we are taking of our panel. And so I am going to ask commissioners to, one, ask one question, despite Larry's training to ask a complex set of questions.

And so I ask everyone to be as concise as they can because I do want to give -- there are some people on my list still that I have not recognized yet and I want to be able to get to everybody.

But, Alta, you are next.

MS. CHARO: Very quickly just on this point exactly. One of the dilemmas in creating a system of some kind of common guidance has been to understand how it should fit structurally within the administrative procedures of the government.

What we now have is a system where we occasionally get that kind of central guidance through "Dear Colleague" and other kinds of letters but it is not coming through the administrative procedure acts, adjudicatory procedures with clear avenues for appeal. It is not being done through rule making.

And so it is confusing how people who are not happy with the advice that is being given can act to appeal the interpretations of the regulations or to request a review of that interpretation, a reconsideration.

So if we are going to be moving in such a direction I think we need to be keeping -- paying close attention to the administrative setting of these things.

DR. SHAPIRO: I agree. Tom?

DR. MURRAY: Thank you, Harold.

I cannot help having the impression that what we have as a system built up over a quarter of a

century or so that resembles in many respects the Ptolemaic universe. It began -- I mean, if someone asked me how do we have -- how is that we have the system we had I would have to explain, well, it began -- it was born in scandal with a few kinds of particular wrongs, some of them quite heinous wrongs that should never have happened, and the whole system was made to deal with those. That was the original design.

And then we say, oh, but this also looks like research with human subjects so let's figure out how to handle that and you say you had a system founded on, you know, built up, you know -- it was justified to have a system. It began as a -- you know, relatively focused idea but it has now tried to form all these epicycles to bring in all these other kinds of human subjects research.

I think we need a Copernican revolution in human subjects research protection and I am going to ask you what you think ought to be at the center. What ought to be the sun in that particular system?

The goals at least that the current system -- basically the Common Rule and the IRB's seem to have are two substantive and one procedural goal. Substantively we want to protect human subjects. I think John Eisenberg just said we want to protect

people at risk. Maybe that is the candidate for the sun here.

We also want to provide guidance to those people who are designing and conducting studies and Norman Bradburn mentioned the MCW ListServer for IRB's. There is also the Journal IRB, which happens to be published by the place where I now work.

And there is a procedural goal. We want to ensure that the interests and views other than those of scientists and institutions are included in the deliberations over what is justifiable and what is not. Those seem to me to be key components of whatever we end up with.

And so my question is what ought to be at the center of that system?

DR. SHAPIRO: Dr. Fry?

DR. FRY: I would like to answer that first. I think your first point, that protection of the individual subject is the kernel of the system -- should be the kernel of the system. But I would also like to add that -- to refer back to the previous comments that I think education, both for IRB members but also for investigators at the level before they get to becoming investigators in clinical and biomedical research or other types of research, ethical --

education and ethics in universities and colleges is a very important aspect to this -- that researchers should be able to put themselves in their subject's shoes and then they might -- I think that helps a researcher determine if what they are doing is ethical or not ethical.

Would they want to do unto others as they would do to themselves?

DR. SHAPIRO: Norman?

DR. BRADBURN: I think I would put risk at the center, the sun and so forth, but not just risk but to use a framework that I am sure Harold is familiar with that is also risk of what. Is what is the horror -- risk is not -- I mean, it is not dichotomous. First of all, it is the probability of risk that things will happen but it is -- but some things are worse than others.

And overall, you know, it is a combination of the probability that something -- some harm will happen but also how harmful it actually is. And we talk -- I mean, in these discussions and not just here but everywhere one talks about risk in the sense that the probability is something is going to happen but there is not -- it is as if everything that would happen is equally bad to people.

Well, you know, the horror cases that you say gave -- mentioned gave rise to it, those are really horrible things. There are a lot of things that might happen that are not so horrible even though the probability that they would happen might be greater.

So we need to take into consideration not only the probability that something bad is going to happen but how bad is it in terms of the consequences and what has happened over time, I think, is that we have learned or at least become much more conscious of a whole range of harms that we had not thought about before. There is not just physical harms of research. There is economic, social harms of various sorts.

But we have all -- we have put them all as if they were equally bad so we only have -- is there some risk non -- like it is the worst case. Is it a non-zero probability that something bad will happen, and it does not matter how bad it is, you come to the same conclusion.

So we have got to get much, much more -- being able to say what -- quantify the risks in some kind of way but also quantify essentially the harm. How harmful it is before you can say is this something we really ought to do.

DR. SHAPIRO: Okay. I have Diane, Steve and

David on my list and then we are going to have to draw this part to a conclusion.

Diane?

DR. SCOTT-JONES: The question that I have is similar to the one that Tom just asked and I wonder what you think would be needed to lead to IRB's functioning in the most productive possible way. Do you think they are fairly easy remedies or do you think the system as it exists now has some basic and fundamental flaws in its way of operating?

DR. EISENBERG: One of the reasons why we asked the Institute of Medicine to study this question is because we really do not know what the best practices of IRB's are and we will soon learn.

I suppose that IRB's can work very effectively if they follow some principles and learn from one another and we are hoping that we can help that to happen.

But I do think, as I mentioned earlier, that having some kind of consultative mechanism whereby there is some guidance -- there is some guidance for the nation about the major areas that the IRB's could use but also that the investigators could use, I think, would be very, very helpful.

DR. SHAPIRO: Thank you.

Steve?

DR. HOLTZMAN: I find this discussion brings us back to many of the major themes we found ourselves facing in the human biological materials report. To go with your Ptolemaic suggestion or what is at the center, and you said risk, I find myself reflecting on the fact in those paradigm cases that led to the regulation there were two kinds of harm if you will. It was the physical harm but there was also the use of people which was the violation of their autonomy.

And therein lies the two strands that are imbedded in the regulation of privacy and confidentiality lining up with autonomy versus protection from harm and wrongs versus harm major concepts.

And that when you say risk lies at the center in harm, you are thinking of harms that come about from discrimination, stigmatization and so the focus and locus of your attention is on the confidentiality protections so that the "and" on the antidiscriminatory measures. And there is another locus which people when they are thinking about the autonomy, which really takes you back to the consent process, even though that consent process, though pure, may not protect against those other harms.

And much of -- when I listened to this discussion, much of the kinds of research that is being talked about here -- let's call it research -- can be constructed in a way in which through coding and confidentiality there will not be the harms. All right. Though there will still be a strand of thought that says there is the potential for people being wronged and misused.

And we need to think through, I think, when you decide to start to take away the epicycles where are you going to focus and to what extent, and the weight will be accorded.

DR. SHAPIRO: David?

DR. COX: So I am really struck by the lack of guidelines, as has been pointed out sort of by all of you, but also struck by what appears to me a really over simplistic view that by having guidelines it is going to fix what happens.

This sort of comes back to what Tom said, too. You know, you have to have people that basically are playing the game. If they are not playing the game you can have all the guidelines that you want and what people are going to be doing most of the time is figuring out how to get around the guidelines.

I think that this is illustrated by the risk

averse behavior of most IRB's today because although there is no doubt of the dedication of people on IRB's, the expertise and the intent to do good. Why is it the case then that in very simple minded cases where everyone around this table would know what an expedited review would be that it is not expedited. We had some discussion about that just a second ago.

So that there is other factors that are driving this besides common sense and I think that until we figure out a way to deal with those factors, simple guidelines ain't going to solve the problem.

Now I am not arguing against having such guidelines but how do we get people to play the game because without that -- it is the same thing -- the point that Steve brought up. Having protections in terms of encryption is not going to solve the problem neither if people do not actually care about protecting human subjects.

So are there any comments about this? I mean, I realize this to me -- Tom, that is my answer to what the center of the universe is.

DR. EISENBERG: Your comment reminds me of the vast literature on medical practice guidelines and why they do not work. They do not work because they are not sufficient but that does not mean they are not

necessary or they are not helpful. It takes opinion leaders. It takes leadership in the organization. It takes a sense of commitment. It takes incentives. It takes a structure which is supportive. It takes skills. I think you are absolutely right. There -- this is not going to be solved by issuing some little pamphlets that says here is how you protect your patients' confidentiality.

I think that, in fact, is a part of the issue here. Is that we have relied so much upon the IRB mechanism that we have assumed in many institutions and many -- that we just do not have to worry about it anymore. We do not have to provide institutional leadership or a national research leadership in this area.

It is what I was alluding to when I spoke to my frustration that more national professional societies have not taken this on as a major issue.

Just issuing a pamphlet from an American Society for blank is not going to be sufficient. You have got to make it a part and parcel of the professional ethos of that organization.

DR. SHAPIRO: Norman?

DR. BRADBURN: I think there are two aspects to protection. The whole system supposedly is set up

to protect the human subject and so forth. As it is working out, it is also other things protecting the institution has come in and I would suggest that that is now dominating the way it is working out, that it has shifted from worrying about protecting the subject to protecting the institution.

DR. SHAPIRO: Thank you.

Eric, by special dispensation you get a question.

DR. CASSELL: Yes, and brief, too.

(Laughter.)

DR. SHAPIRO: I hope so.

DR. CASSELL: What David said and what you have been saying really leads to this understanding that the increasing bureaucratization of the process, which is what guidelines are always an attempt to do, to bureaucratize it because you cannot depend on individual people, which makes it even more bureaucratic, which makes it even less dependent.

And when you said all these things -- the guidelines would really work if you had commitment and da, da, da. When you have all that you do not need guidelines.

DR. EISENBERG: I disagree. Let me pursue my rules of the road example. Let's imagine you took

every 16 year old who was applying for a drivers license and they went to the Bureau of Motor Vehicles and they -- and you had them sign a form that said that they will do the following, and they were responsible for coming up with all the rules that they were going to follow when driving.

They would have to remember that they drive on the right-hand side and they have to park a certain number of feet away from the car in front of them. They would have to come up with all that themselves.

We do not do that. We give them a set of guidance. We tell them these are the rules but we all know that just giving them the rules is not good enough.

My point really is that for the average investigator, the average investigator has to come up with the rules himself. He has to -- or the institution has to derive the way in which they will conduct research in an ethical way by themselves.

Now the -- I think in some ways the area of confidentiality and privacy is the easier one because it has gotten a lot of attention.

There are other areas. I raised one like the contractual relationship between an investigator and a corporate sponsor. It is one that we have not given as

much attention to. There are lots of other areas where I do not think we have provided enough guidance.

And I am by no means suggesting that we just issue a bunch of checklists and that we assume that because you check it off that you are going to conduct research in an ethical manner but I do think we need to have some rules out there, some guidance.

DR. CASSELL: Yes. Well, the thing about argument by analogy, you know, is the analogy has to be a good one. So I am going to tell our -- I am going to tell our IRB that they are really like issuing driver's licenses to teenagers, and I am sure they will find that amusing.

(Laughter.)

DR. SHAPIRO: All right. Thank you very much.

I do not know how to answer myself Tom's question of what is the center of this universe but I -- the issue that always come back in my mind -- I do not know if it is the center or not -- is we find ourselves dealing with vulnerable -- people who are vulnerable for one reason or another.

They are vulnerable because they are uninformed. They are vulnerable because they may be exposed to risks. They are vulnerable for various reasons and in that case I wanted to ask one question

myself.

And that is -- perhaps Norman or John -- in dealing with survey questionnaires or gathering information about people who are employees by employers, gives -- it feels very different to me than gathering, let's say, information by some third party just because there is an automatic dependence here.

And the question I am trying to formulate in my mind is, is there anything special about that situation where, in fact, you are gathering information, whether it is work or health maintenance type of things, and not in the sense of HMO's but in terms of health in a factory or a production facility. It is very hard for someone to say, no, I am not going to provide this information, it seems to me.

As opposed to when you get this anonymous phone call at 6:00 o'clock at night. When you do not want to answer you just hang up the phone. That is easy. You are not vulnerable in those situations it seems to me. It is the questioner who is vulnerable.

Do you have any observations, Norman or John, about that?

DR. BRADBURN: Well, I think when the person -- the researcher or the person gathering the data has fate control over the person they are getting the data

from, it is quite a different situation than when it is an outside person.

So even when you are doing -- I mean, companies that do employee surveys usually are quite careful to get an outside group to do it at least and work very hard to make sure that the data are not individually identifiable.

Now people often do not believe that. I mean, they do not even believe the census is confidential. But, you know, you can only -- you can try to do the best you can but if you have got fate control over the person and you are asking them stuff that they know can be used that way, it is very hard to convince them you are not going to use it.

DR. SHAPIRO: Okay. Well, thank you very much. I really want to thank you, all the panel, for giving us the time today. It has been very, very helpful to us. We are very grateful to you and so thank you very much.

We will take a break now for about 10 minutes and reassemble as close as we can to ten minutes before the hour.

(Whereupon, a break was taken from 10:43 a.m. until 11:03 a.m.)

PANEL II: DEFINITION OF RESEARCH

SOCIAL SCIENCES AND HUMANITIES

DR. SHAPIRO: Okay. I would like to begin our second panel. We are still missing one person from the panel but he indicated the schedule would give him some problems. I hope that he will be able to join us as we have our discussion.

We want to continue in some sense our focus on the definition of research by which we mean when does the oversight process get initiated and for what kinds of activities should it be initiated and, if so, in what way.

We again have a wonderful group of very experienced panelists to speak to us on this and with whom we can have some conversations. I want to thank you all for coming. It is a great pleasure to have you here. I will again from my left to my right and ask each panelist to present their views and, of course, we will go in the same way.

We will ask any clarifying questions if there are any after your presentation is done and then we will go to questions subsequently.

So let me turn first to Professor Wax, who is Professor of Anthropology, Emeritus I understand. Thank you.

DR. WAX: Thank you.

DR. SHAPIRO: You are welcome. Thank you for coming.

MURRAY WAX, Ph.D., PROFESSOR EMERITUS OF ANTHROPOLOGY, WASHINGTON UNIVERSITY

DR. WAX: In 15 minutes, outlining the ethical issues confronting a discipline is rather like asking someone to produce a sound bit to resolve a major social problem like global warming. Ethically, the enterprise becomes somewhat questionable.

Nevertheless, I shall begin with a sound bite. Although it is a simplification, I believe it is nevertheless true: The gravest ethical problem facing the people studied by anthropological research is posed by unknowing and overzealous IRB's and by governmental regulators attempting to force qualitative ethnographic studies into a biomedical mold.

I realize that many, perhaps most of you, have devoted many years of your lives to the ethical problems that emerge within biomedical and related researches. The problems that emerge within anthropological researches are equally or even more demanding because they have to do with human beings, not just a physiological specimens, but as social creatures living in families, clans, groups, tribes or nations.

The ethical problems of qualitative social research are especially challenging because our predominant ethical theories -- Kantian and utilitarian -- focus upon social atoms or upon a population of social atoms, rather than upon human beings who are organically related to other human beings, living, as I have said, within groups, communities and institutions.

I am not arguing that anthropologists are morally superior to other scientists I do argue, however, that the risks and benefits to the people they study are very different from those faced by the subjects of biomedical research.

Let us note that I am not going to discuss ethical issues in one form of anthropological research. I shall not be considering archeology, linguistics, physical anthropology, primatology; nor the issues involved with museum collections, the handling of skeletal and bodily remains, the treatment of nonhuman primates.

I am going to focus upon the type of social research known variously as ethnography, fieldwork, or qualitative social research. It is a method - really a group of research procedures -- used by all sociocultural anthropologists, some sociologists, some social-psychologists, as well as a few resaerchers in

other disciplines, such as oral history.

It overlaps with depth journalism, interviewing in clinical psychology, and with the everyday conversations of ordinary people. In classic anthropological studies, the research may continue for months, years or even a lifetime of intermittent visits. However, in more contemporary situations, the research periods are considered -- often considerably shorter.

The typical product of ethnography fieldwork is a book, a monograph describing in detail some aspect of the life of a group or community. In classic anthropology, it might have focused upon or come to focus upon some aspect of a relatively isolated and technologically primitive community. The system of kinship and marriage, law and conflict resolution, childrearing, production and exchange.

In contemporary research, the book might describe the web of exchange of goods and favors in Red China; or the lives of women in Cairo; the activities of a group of drug dealers in New York City; the work, lives and problems of women surgeons; or how a community of Sioux Indians deals with the problems of educating their children.

Throughout much of the 20th Century there has

been continual debate about the scientific status of this set of research procedures. Our issue here today is not how scientific these methods are but how profoundly and, in particular, how ethically they differ from the methods used by biomedical investigators.

In biomedical and related research the cast is typically divided into research investigators and research subjects. Far in the background are a professional audience and a wider public.

The research subjects are subjected to research procedures, which often are invasive and physiologically consequential.

In ethnography field work the cast is similar but different because usually there are gatekeepers who control or limit access and because the persons who are studied might better be described as hosts. In the far past, those studied were often labeled as informants. In the idealistic present they might be labeled as research partners. I will use hosts.

Gatekeepers and hosts usually have considerable power and authority in relationship to the investigator. The researcher endeavors to construct social relationships with the host people so as to observe, listen, talk, possibly inquire, possibly

participate in as much of the round of lives as both parties can tolerate. That is the range of social, sociable, ceremonial activities.

In ethnographic research the crucial problem is not what the fieldworker does to or with the participants but what happens to the research data and products. The hazard is easiest to visualize if one imagines an official of an authoritarian regime deciding arbitrarily to confiscate whatever notes of the fieldworker that can be located.

While this is vivid in the case of a foreign and authoritarian government, it may also occur through the order of a U.S. court when a prosecutor discovers that an investigator say has been studying persons engaged in activities deemed illicit or deemed consequential to some political cause or legal case.

This is especially noteworthy when an investigator may be studying drug use, or juvenile delinquency, or other activities considered significant.

Fieldworkers go to considerable lengths, usually to conceal the identities of persons or communities under study but their safeguards can be breached.

The intent of the human subjects regulations

is to protect the weak and powerless. Within the arena typical of university based research, the powerful are the aristocracy of research in biomedicine and natural science. The next level are behavioral scientists using formal statistical procedures and toward the bottom of the food chain are the isolated investigators who utilize qualitative methods.

There is a natural tendency for institutions, who are risk aversive, their legal staffs, their IRB's, to protect elite access to federal funding by formulating their human subjects procedures so as to safeguard the projects of the aristocracies and then bureaucratically apply the regulations to all projects regardless of how appropriate they are or whether or not they might safeguard the subjects.

The effect upon qualitative projects is that the IRB's and the regulators to whom the IRB's must report join the ranks of gatekeepers by imposing requirements that undermine the autonomy of the hosts and might even harm them. Disregarding the actual ethical issues, the regulators wish to safeguard the $50 million project by subjecting the $50,000 projects to project requirements that are irrelevant. Let us see how this can happen.

Amelia Rodriguez, a pseudonym, was raised

within a modest family in South America, then completed her higher education in this country. After a career as a registered nurse, she became a medical anthropologist securing a position on the staff of a medical school, one of whose principal missions is service to the local Hispanic community.

As an Hispanic from humble background, she has been highly successful in studying the health problems of this community and developing innovative programs of health education and assistance. In the course of her research, she encountered the Curanderos. The native healers, the folk doctors, who provide the local Hispanic community with medical advice, diagnosis, prescriptions, treatments.

Using her considerable social and medical skills, she managed to develop rapport with a number of the curanderos, was consequently in a position to study them, and learned how they defined and handled various conditions.

When she reported this achievement to the administrators of her program and they, in turn, to the IRB, she was instructed that she must secure from the curanderos signed papers of informed consent. To Amelia's credit, this action was one she would not doe. The curanderos have very good reason to keep their

identities concealed from figures of authority.

Some are illegal immigrants. Depending upon local law, they could be charged with practicing medicine without a license. Most are illiterate. Most have a poor command of the English language, limited understanding of what might be implied in signing any sort of legal form.

Only, too often, in research investigations, as you know, the gaining of informed consent from a research subject is translated into securing a signature upon a legal document. The document does not have anything to do with informed consent as a social, educational, moral process. Rather the function of the document is to protect the research institution from the regulators of the Federal Government and the possibility of lawsuits for mistreatment or malpractice.

In the case of Amelia's researches, the legal document bewilders the signatories and offers no genuine protection.

When the persons studied are engaged in activities that they wish to keep confidential, the signed document becomes a weapon that may be discharged against them. Various kinds of legal procedure, including criminal process, can be used to breach the

secrecy that a conscientious researcher might wish to maintain. Not only cases of illicit activity but, for example, because many communities have rituals and ceremonials, which must be maintained a secret.

It is a separate issue but I should mention that, for example, traditional Hopi believe that incautious words or actions involving ceremonial items could wreak havoc in the universe.

Traditional Australian Aborigine men are convinced that women must be shielded from observing their ceremonial objects and rituals.

Traditional Navajo have important taboos concerning their rituals.

Note the inversion of the configuration of biomedical research. In the case described, it is the researcher, Amelia, who is the supplicant vis-a-vis the curandero. She is encountering him or her on his ground in his territory where he or she needs nothing from her. Also, and most important, the danger to the curandero would not directly follow from any of her inquiries. Whatever hazards or dangers might ensue would come from her communications, and in most instances of ethnographic fieldwork,the possible risks are quite unpredictable. One thing is certain, the risks multiply considerably if the identity of the

individual is made available.

Amelia spent many months in anxious negotiations with her university administration. Finally she was ingenious enough to gain the agreement of a few administrators to the following: That at the start of a tape recorded interview, the curandero or curandera would confer a blessing upon Amelia's research activities rather than identifying himself or herself and, thereby, stating consent.

But, unhappily, Amelia had had to waste precious time scheduled for research in hassling with administrators about an investigation basic to the institution's mission. By the time the research with curanderos received some partial approval, a major portion of the funds budgeted for transcription and translation were no longer available. A further consequence was that her graduate students were frustrated in their apprenticeships.

Unhappily, also, her reports were then sanitized by other administrators and federal granting agencies. Her informative narrative of the health roles of the curanderos was then abbreviated on the grounds that they had not signed a legal piece of paper and so had not given consent. Furthermore, it proved to be the case that of the Hispanic patients utilizing

the clinic for a particular disorder two-thirds were also consulting curanderos. This fact also proved uncomfortable in view of the lack of informed consent and so it was removed from her report.

I do not have time to enter into other troubling issues. For example, there is the role of gatekeepers, who regard themselves as having the responsibility or authority to determine whether or not a group or community may be studied.

The issue takes one form when one deals with a dictatorial and authoritarian regime, another form when one deals with a democratic authority. For example, an Indian Tribal Government, where a new party comes into power and revokes the permission granted by the previous one. Still another form when one deals with a school or prison whose administrators can hole the researcher at bay.

IRB's are trained to protect the flow of grant monies by imposing federal regulations upon researchers. Their efforts are seconded by institutional attorneys who wish to protect their employers from lawsuits by aggrieved research subjects. The efforts of the IRB's and the attorneys can have useful consequences in some cases. They can have harmful consequences in others.

The most recent threat to ethical research has been a congressional statement that the Federal Government is entitled to the data generated by the research projects it has funded. Fortunately, this time, with protest from some of the professional disciplines, the threat was averted or at least made ameliorated for anthropological type inquiries.

However, in the present climate of law and opinion, a researcher who wishes to protect the privacy of research hosts is usually well advised to store the research data in a foreign country where it would not be vulnerable to a legal process.

Thank you for listening. The paper was authored not only by myself but by Joan Cassell, who has done recently research upon women who are surgeons.

DR. SHAPIRO: Thank you very much. Just as we have done before, if there are any clarifying questions we would go to them. If not we will -- Tom?

DR. MURRAY: Professor Wax, you made a -- if I understood your claim that in the case of the study of the curanderos, the fact that two-thirds of the Hispanic patients at this clinic were also seeing curanderos, was somehow -- was forcibly omitted from the researcher's report.

DR. WAX: Yes.

DR. MURRAY: Having something to do with consent or IRB's. What I do not understand is the connect there.

DR. WAX: I am not sure that I understand the connection either, Tom, but this was what Amelia reported to me that --

DR. MURRAY: It just makes no sense why they would do it simply -- why that piece of particular finding would be omitted and others would be permitted.

DR. WAX: I cannot answer that but I would -- if you are interested in pursuing it with Amelia, give me your name and address, and I will ask her if she would like to respond to you.

DR. SHAPIRO: Clarifying questions? Is it a clarifying question, Alta?

MS. CHARO: I just want to make sure I understand the bottom line lesson that you want us to draw from this story, if I may, Dr. Wax.

DR. WAX: Yes.

MS. CHARO: It was not that the regulations themselves were incapable of handling the problem because there is a wavier of consent for minimal risk research where consent is impracticable. It is that there are institutional pressures that will drive IRB's to not take advantage of those openings that are made

available through regulations?

DR. WAX: Yes.

MS. CHARO: Thank you.

DR. WAX: Yes. I think IRB's, to use a previous statement, are risk aversive and the Federal Government comes in with a club and says, "We will terminate all research grants to this place." I think also my own experience, I must say, is that informed consent has nothing to do with informed consent.

DR. SHAPIRO: Thank you very much.

Professor Sieber, if you do not mind, I would like to go to your colleague to your left first because I know he has fit in this panel between two other meetings, at least that is what I was told, and I appreciate the effort.

And so if you do not mind -- I apologize but if you do not mind I will go to Professor Abowd for his remarks and I will take a few questions after you remarks also. And then if you have to leave, we will be grateful for the time you have been able to give us.

Professor Abowd?

JOHN M. ABOWD, Ph.D., Professor of Economics, AND DIRECTOR, CORNELL INSTITUTE FOR SOCIAL AND ECONOMIC RESEARCH, CORNELL UNIVERSITY

DR. ABOWD: Thank you very much. I do have a

1:00 o'clock meeting at the Census Bureau so that is the constraint.

(Slide.)

I was asked to prepare some comments to this commission primarily based on a referral that you received about my expertise in dealing with business and individual data rather than my expertise in dealing with institutional review boards, which I will confess at the beginning of my talk I have relatively little contact with because this is the sort of research that in the past has not gotten a lot of scrutiny from the review board. So what I thought I would do was state briefly what people are trying to do with this kind of research, why it represents a challenge to the research community.

(Slide.)

And then give you one prototype, which I think I can do relatively quickly, and then go through the privacy, confidentiality, scientific merit and burden issues that surround it, and then I will stay for as much of the question and answer session as I can.

(Slide.)

I am on slide three.

(Slide.)

The kind of research that we are talking about

here is the creation of what are called linked business and individual data files. The challenge is to construct safeguards for the personal privacy or business privacy and confidentiality that permit us to get the social benefit from the research when that is appropriate.

I want to stress that I have a lot of international experience here working with data from other countries and different societies weigh the costs and benefits to these kinds of research projects quite differently and as a consequence they make choices that vary on the scale of how much to make timely statistical information available and how much to protect privacy and risk of loss of confidentiality.

I should say that all of the governments that I have worked with protect privacy and confidentiality very strenuously but there is no such thing as a fool proof system. I think everyone accepts that and the issue is how you mitigate the risks associated with violations of privacy or loss of confidentiality against the benefits to society from making research use of these valuable data.

So a prototype of the kinds of projects that I work on and many other researchers work on is on the next slide, slide four.

(Slide.)

Essentially, what happens here is you are going to combine data that was collected in essentially three generic settings. On the left is the household data which typically consists of information about the household. I scarfed this slide from a more technical presentation. That is why it is called a record.

So information about the household and some identifier that is placed on that household, which is the sort of thing that you would want to protect the confidentiality of. So you can think of it as either an exact identifier or the name and address of the respondent household. And, of course, there is data that is measured at the household level. If there were not, there would be almost no point in this exercise.

The individuals who are members of that household are identified by another kind of identifier that you would want to protect the confidentiality of and, of course, they also have data associated with them and it has been very common in surveys of the household sort to be able to associate the individual to the household. That is not an unusual thing. In fact, nothing about the household data by itself is unusual.

The business data would typically be collected

from businesses, entities defined according to the purposes of the study so they might be based on a geographical sampling frame or they might be based on a financial sampling frame or they might be based on an employment origin sampling frame.

There is some identity ID associated with the business data that is at the core of the confidentiality and privacy associated with those data and, of course, there is information about the businesses.

And to combine them you go to what I have called the "link record" but it would be better described as a link source so what a link source does is it -- is a relation between the identity of the individual typically and the identity of a business.

Common link sources would be things that describe an employment relation so the individuals, the employee, and the businesses, the employer; things that describe a commercial relations so the individual is a client and the business is the provider of a service.

So by way of the link record it is kind of obscure. The link record typically also contains some data. Usually data about the association between the individual and the business.

By way of the link record or the link

mechanism, which might be statistical rather than exact, you are able to associate data that were collected from a household with data that were collected from a business. And in many cases these are repeated surveys or longitudinal surveys or censuses on both sides of this prototype.

Okay. So now I would like to just basically talk about what I think of as the four sets of issues that surround the use of these data and let's start with privacy so that is slide five.

(Slide.)

Generally speaking, the privacy issues associated with the household and business data were dealt with at the point at which the original information was collected from the appropriate source and so the informed consent for statistical uses was given by either the household or the person as appropriate on the household side and the business on the business side.

Almost always under assurances that the identity of the respondent would be protected and the resulting data would be used for statistical purposes.

Generally, statistical purposes is described very broadly. It means to study issues related to the questions that you are being asked or the information

that you are being asked to provide. So the household and the business data when they come from surveys have their privacy protections done at the source.

The link record, on the other hand, often comes from confidential administrative data and so its research use is generally authorized by law rather than by the informed consent of the provider so that, as you know, there are research -- there is research that goes on in many places using confidential administrative record data and it has been directly authorized by law.

So the privacy protections that enter in now are exactly what sort of informed consent did the households, the businesses and the providers of the administrative data give when the database object, this set of linked relations was not something that was collected from any one source so those are the privacy issues.

The confidentiality issues -- that is slide six.

(Slide.)

The key confidentiality issue is the first bullet. The respect -- protecting the respondent identity, either the business or the individual, almost always precludes the production of a public use file from data of this sort. It is demonstrably too easy to

mine the public use file to recover sufficient information to reidentity at least some of the respondents and virtually all of the statistical agencies with which I have worked have shied away from creating public use files of this kind of data product.

Consequently, you need a protocol for scientific use of the confidential data and generally that protocol is some sort of restricted access for a scientific project. That restricted access normally involves a scientific merit review and then a set of protocols that the researcher agrees to, the institution housing the data may also agree to them, and this is often where institutional review boards get involved because if there is a protocol associated with the confidentiality of the data then you want to certify that that protocol does what it is supposed to do, that you are capable of abiding by it, and that you can monitor the provisions of the protocol. And that protocol generally covers what we would have called in the past secondary data analysis of the existing database.

A much stricter protocol, computer scientists talk about firewalls and various sorts of layers of confidentiality protection, surrounds the environment where the actual data product is created. And that

kind of protection is generally accomplished by giving very restricted access to a small number of people and never releasing the identifiers that are used for the link beyond that confined environment.

At the Census Bureau they like to call it a firewall within a firewall within a firewall because very few people even in the Census Bureau would have access to such an environment, although the research access might be granted to the data product subject to the protocols we have talked about a second ago.

So those are the confidentiality issues.

(Slide.)

The scientific merit issues -- there are basically two. Usually proposals to either create or use such data are peer reviewed. I know of peer reviews by NSF and NIA but I am sure that there are people in the room who can describe a lot of other peer review processes that might be used here.

The peer reviewers, unlike their access to a public use file from which they could assess the quality of proposed research have to assess the proposal based on a description of the process and perhaps some limited access to results from the process but they are not -- the scientific merit review depends upon multiple access to the confidential data product

in order for it to be a reasonable review process.

By their very nature what you are doing is you are creating a monopoly product that you have to then manage the access to because you are trying to balance the privacy and confidentiality against the research merit.

On the other side of the coin is these datasets have been created in order to address some astoundingly important public policy questions, social security and aging research, welfare to work programs, a lot of analysis of labor markets. That is what I am most familiar with but also in the health care are.

So there is a strong cry for information that can be used to addressed these public policy questions that has to be balanced against the difficulty associated with creating and maintaining the restricted access linked data product.

(Slide.)

And a final issue that I want to draw your attention to is the question of burden and that really has two points. The main reason that one tries to combine information from individual and business sources is because it is enormously burdensome to ask either set of respondents to provide that information directly.

No matter how capable you think a business' information technology system might be, asking for very detailed information about the employees is burdensome.

Similarly, it is burdensome to ask an individual about the information associated with his or her employer.

Furthermore, it has been shown that the information that is directly provided about the other side of the link if it is an employer/employee link or if it is a customer client, client/provider link rather, that information is not as reliable as the directly provided information and so it subjects the analysis to more error.

Okay. I realize that as a commission you are pressed for time and I thank you for giving me 15 minutes. I did leave copies of the presentation for you and I will take clarifying questions now.

DR. SHAPIRO: Thank you very much.

Is there any clarifying questions at this moment anyone would like Professor Abowd?

Okay. I hope you will be able to stay for as long as your time allows and thank you very much for fitting us in.

DR. ABOWD: Thank you.

DR. SHAPIRO: Let me turn now to Professor

Sieber.

Professor Sieber, welcome. It is very nice to have you here.

JOAN E. SIEBER, Ph.D., PROFESSOR OF PSYCHOLOGY, CALIFORNIA STATE UNIVERSITY, HAYWARD

DR. SIEBER: Thank you. It is very nice to be here and I appreciate being asked to testify. I have spent many years trying to explain to psychologists what the federal regs might have to do with their research so I think I am ready for this.

DR. SHAPIRO: I think we are ready, too.

DR. SIEBER: Okay.

(Slide.)

I am going to address actually eight issues. The definition of research, privacy, confidentiality, and five aspects of informed consent. The definition of research in the regs serves psychology very well for a roundabout way.

Specifically, it is true that psychologists use research methods for many activities that are not research according to the regs and, in fact, psychologists do all the things that the preceding panelists have talked about. However, it appears that in most cases at least, and I will be directing my remarks primarily to academic psychology, that

departments work fairly closely with their IRB's so that the things that are nonresearch but using research methods where subjects may be at risk are reviewed and the ones that are not, are not. I can talk a little further later if you would like about some of the mechanisms of lower level review that are light-handed but appropriate.

(Slide.)

So let me turn now to the really meaty issues here. Words are very powerful and words such as privacy and confidentiality are very poorly and inappropriately defined in the regs.

(Slide.)

And the result is that the sophisticated IRB has to explain and explain and explain how they will flexibly apply those regulations.

(Slide.)

The researchers who are not particularly sophisticated, those that are not -- that have not been through this process a lot feel confused and cynical, distrustful of the IRB and regulatory process because it really does not seem to apply to them.

(Slide.)

And, unfortunately, there are unsophisticated IRB's that are readily confused, very risk averse, very

heavy handed.

I am going to be talking a bit about how poorly the definition of confidentiality is dealt with. In that connection I want to say that I often give workshops for PRIMR, Public Responsibility in Medicine and Research.

(Slide.)

And I shall always remember the IRB administrator who came up to me after one of the little workshops on confidentiality and said to me, "We always require absolute confidentiality." And I said, "Well, what do you mean by confidentiality?" And she said, "Oh, you know, confidentiality." She said, "Not to tell."

And so I think we really owe it to researchers and to IRB's to be very clear about what confidentiality is.

The definition of privacy that is given in the regs is very long and arcane and I could not even get it all on a slide.

(Slide.)

But it confuses privacy with confidentiality, which may be okay with regard to medical records but not -- well, it is not even okay there. And it also ignores utterly the concept of personal privacy.

(Slide.)

And that is a concept that is very vital to psychological research.

(Slide.)

It would be better to define privacy as referring to person's interest in controlling the access of others to themselves. Note that privacy refers to persons and confidentiality to identifiable data.

(Slide.)

The ability to regulate access of others to one's self varies with many things as I believe Murray Wax as already alluded to. It varies with the person's -- the subject's status and role and degree of verbal skill. You may know very well how to deal verbally to protect your privacy. It also is a function of one's stage of psychosocial development, the context of the research, the culture, and the technology of the research.

I would like to give some examples of personal privacy issues in research.

(Slide.)

The first one is a technology issue. A hidden camera that will videotape continuously will preclude the possibility of protecting yourself from others.

And the subject's need to be warned in the consent that this is going on so that they can monitor their own behavior and not do things that they do not want to be captured on videotape.

(Slide.)

Now here is a psychosocial issue. A young child would want a parent present at a session with the researcher but a teenager has quite different issues of personal privacy, can handle the researcher but certainly would not want the parent to be present.

(Slide.)

Appropriate respect for personal privacy has major implications for a lot of important things in research. Certainly for the ethical treatment of subjects, their candor, the ease of recruitment, the validity of the research, and finally the respect by the subjects and anyone else who knows about the research for the research process.

(Slide.)

Now the code does not define confidentiality and it confuses it with privacy. It assumes that everyone has the same concern about other's access to information about themselves and it assumes that confidentiality means an agreement not to disclose and these are all poor assumptions.

(Slide.)

Confidentiality is not an agreement not to disclose. Confidentiality refers to any kind of agreement about disclosure. I mean, as an example, there is even an extreme case of a case study research in which the subject refused to participate unless his full name and identity appeared in the publication that was to follow.

Confidentiality depends on methods for controlling access of disclosure which Professor Bradburn discussed very capably. I will not go into them. Only to remind you that they are very consequential and that they need to be kept in mind in any discussion of confidentiality in the informed consent or elsewhere.

And some of those methods are imperfect so that some agreements may not remain valid and consequently any confidentiality agreement needs to reflect all of these realities of the situation.

What the subject wants, what the researcher wants, what the limitations are of the mechanisms for controlling access.

(Slide.)

A good definition of confidentiality would state that -- let me --

(Slide.)

I am sorry. Here. A good definition of confidentiality would lead researchers to the literature on methods of controlling access and to understand how to make appropriate and valid agreements about the control and access of data.

(Slide.)

A good definition, thus, would be that confidentiality refers to data and to agreements about who may have access to identifiable data and what methods will be used to control that access. That does not appear in the federal regs.

(Slide.)

Informed consent, turning now to these issues, is required to include an explanation of the purpose of the research.

(Slide.)

Now suppose the researcher said, "We are going to study your conformity behavior when you make decisions with your peers." You will see that one subject is thinking, "Well, I am not a conformist but the rest of these folks are." Well, actually they are all thinking that.

There are a lot of major social issues such as conformity and antisocial behavior that cannot be

validly studied if subjects know the exact purpose of the research so there needs to be sometimes some concealment of the exact purpose.

(Slide.)

Researchers who need to conceal may use various ethical approaches, including prior consent to concealment with later debriefing or the approval of surrogate subjects of what they are going to do. And the debriefing that is done certainly needs to be sensitive so these are all areas of research or education that are important.

(Slide.)

A better statement here might be that what is required is an explanation of the purpose of the research or if the research cannot be done validly when subjects understand the purpose, a more general description of the topic and an accurate explanation of what will be asked of the subject, in other words what their experience will be, and researchers certainly should not be allowed to conceal information that would affect subjects' willingness to participate.

(Slide.)

Let me turn now to risks as they are dealt with in the regs. The regs call for a description of any reasonably foreseeable risks or discomforts to the

subject and this rather ignores demographic and psychological determines of risk.

(Slide.)

For example, needless worry. Subjects may worry about risks that the researcher has prevented and does not mention in the consent. For example, this undocumented migrant farmworker needs to know that his name will not go to the INS and he needs to know that through procedures that will be believable to him, and there are ways certainly that that can be done that are very culturally sensitive.

(Slide.)

A more inclusive statement about risk would remind researchers and the IRB's of foreseeable and relevant risks, including those that are imagined by subjects, likely to be imagined, and those that the researcher has prevented. It would also remind them that there are certain populations that are more vulnerable to risks than others, including risks of needless worry. It would remind them of ways to ameliorate and prevent risk and also of ways to communicate effectively with subjects about such risks.

(Slide.)

A better statement might be a description of any reasonably foreseeable risk, harm, loss or damage,

including inconvenience, physical, psychological, social, economic or legal risks or discomforts to the subjects or others as a result of research participation and a description taken -- a description of steps taken to ameliorate or avoid those risks.

(Slide.)

I would like to turn now to the area of benefit because this is a -- I think that this is a very different issue in the social sciences and especially in psychology and I suspect that Murray would agree in anthropology.

The regs say that there should be a description of any benefits to subjects or to others which may reasonably be expected from the research. Well, the biomedical researcher may cure the person or pay the person but the psychologist typically is not going to be doing either of those.

(Slide.)

Here is sort of the reality. The researcher is saying -- perhaps this is a master's degree student or a Ph.D. student. "This research is going to help show how children should be disciplined effectively." And the subject is there thinking, "You mean this research is going to get you a Ph.D."

(Slide.)

The typical reality is this, and I think this is true of all research, that the research will add little at the margin to the extensive existing literature on the topic. However, before even collecting the data the researcher knows the literature on the topic, knows a great deal about the topic, and knows of many resources for the general public about the topic, like summaries and bibliographies and films and local workshops, and the researcher could easily share these kinds of in kind resources. You know, the subjects are giving information, the researcher can provide reciprocally information.

(Slide.)

Researchers can provide so many benefits to subjects and to their community, why promise only long-term or unlikely benefits or pay people a pittance when it is so often practical to provide useful information and resources to subjects and to their community.

(Slide.)

So that a better statement might be a description of any benefits to subjects or to others which may reasonably be expected from the research itself or which have been arranged for the benefits of subjects or their community.

(Slide.)

I want to turn now to assurance of confidentiality and the informed consent requirements say that there should be a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.

(Slide.)

We have talked about confidentiality quite a bit so let me just go quickly to what a better statement might be. It might be a statement describing the conditions of confidentiality of identifiable data, who will have access to the data, what safeguards or methods will prevent or reduce the likelihood of unauthorized access, and what unavoidable risks of disclosure may exist.

Of course, one need not go into all of that where confidentiality is not a big issue and I am not -- I have not formulated this statement as carefully considering all possible kinds of research. That is one of the more problematic areas yet in my mind but that would be the most extreme statement that I think would be appropriate.

(Slide.)

Now let me turn to research -- to treatment for injury. The regs say that for research involving more than minimal risk an explanation as to whether any

compensation or an explanation as to whether any medical treatment are available for injury.

(Slide.)

Now in psychological research there is much more likely to be emotional than physical injury.

(Slide.)

Those likely to experience some emotional upset during the study may want to know whether counseling will be available afterward.

(Slide.)

And I think that is something that can very readily be mentioned in a statement about treatment for injury.

(Slide.)

In summary, social and behavioral research methods are now common to all fields of research, including medicine. And the recommended changes, it seems to me, would benefit IRB's, researchers and students in all fields of human research.

(Slide.)

My specific recommendation is that there be more comprehensive regulations pertinent to all human research and a web site then could provide detailed guidelines in education, indexed perhaps by discipline, method context and subject population.

And, hopefully, this kind of information could be of use to educators and it would be much more available to individual researchers in preparing to deal with their IRB and it would also be available to researchers to combat an overzealous and risk averse IRB that did not understand what the researcher was about.

Thanks a lot for the opportunity to testify.

DR. SHAPIRO: Thank you very much for those very helpful remarks.

Let me see if there are any clarifying questions. Tom?

DR. MURRAY: Dr. Sieber, thank you very much. Two quick clarifying questions. One is you talked about research that employs concealment. Did you mean to draw any distinction between that and what is more typically referred to as deception research? That is question number one. Let me just follow with the second.

The second is you also referred to a practice of seeking approval from "surrogate" subjects and I just wonder if you could explain what those are since it is hard for me to understand how informed consent could be given by a surrogate subject.

DR. SIEBER: Yes. Let me take the first

question -- the last question first. The surrogate subject does not give informed consent. the surrogate subject is given an opportunity to go through the procedure as a subject and a surrogate subject is a peer of the subject population and says, "Well, I really cannot imagine --" you know, consent -- it is not consent. It is sort of approval. It would be to say, "Well, I really cannot imagine that any of my peers would object to this."

I also talked about consent to concealment and a prevalent practice now is to tell subjects, "We cannot tell you exactly all about the research before you participate but you will be debriefed right afterwards."

Now to your prior question there are two kinds of deception. One is informational and the other is relational. At least that is one of the ways in which philosophers have talked about this.

Relational is where I owe you the truth and I have not given it to you. Informational is where I conceal something and reveal it to you later.

And you are asking a very good -- a very interesting question because I think that the kind of deception that people generally really object to is relational and I think, for example, that that is the

thing that upset people so much about the Nogrim study. The belief was that this was a researcher who was asking you to be a research assistant and actually you were the subject and you were pressured to do something and under the pressure of duty and working for this important researcher you did it but you were sweating bullets and that was a pretty rough experience for subjects. And I think that is a very good example of highly objectionable relational deception. But there are other kinds of relational deception that are not -- where the consequences, you are not being given an opportunity to do something awful.

A study by Alice Eisen a number of years ago is a very good example. She wanted to find out if subjects who had had a nice experience would be nicer to other people later.

And so it was exam time and there was a study area at the university and someone presumably right out of the dormitory kitchen came by with these great chocolate chip cookies and would give a cookie to somebody sitting there studying. And then a few minutes later someone else would come along and right beside that person would drop their books and the question was would the person be more likely to help them if they had a chocolate chip cookie.

(Laughter.)

I think that is relational deception but I do not think it is bad and so I think that we have to make a second distinction that if it is relational deception it needs to be involving you in doing something that you would not feel good about if you understood the true circumstances.

DR. SHAPIRO: Thank you. Any other clarifying questions?

DR. CASSELL: Did it make a difference, Dr. Sieber?

(Laughter.)

DR. SIEBER: Yes, it turns out that it made a tremendous -- she has written extensively about this. It is as though there is an accountant in the sky and if someone does something nice for you to pass it on. Of course, if someone cuts you off in traffic you may cut off the next person.

DR. SHAPIRO: I will refrain from asking something about the quality of these cookies in any case because --

(Laughter.)

DR. SHAPIRO: We will go on to our next panelist who is a historian, Ms. Linda Shopes.

Again, it is very, very nice to have you.

Thank you very much for coming. We look forward to your remarks.

LINDA SHOPES, M.A., HISTORIAN, PENNSYLVANIA HISTORICAL AND MUSEUM COMMISSION, ORGANIZATION OF AMERICAN HISTORIANS AND AMERICAN HISTORICAL ASSOCIATION

MS. SHOPES: Well, good morning and thank you for the opportunity to speak to you today about the concerns of professional historians regarding current regulations governing research involving human subjects. I should say that this is something new for historians. We are only beginning to grapple with the fact that we need to conform to these regulations.

Four historians, "human subjects" research means oral history, that is, preplanned, open-ended, in-depth, and generally tape recorded interviews with men and women whose first-hand experiences are deemed of some historical significance.

The term oral history itself is maddeningly imprecise. It refers to both the process of interviewing and the recorded interview, in both its taped and transcribed forms.

Although the transmission of knowledge about the past through the spoken word is probably the oldest way in which human beings have learned about history,

historians generally consider oral history as originating with the work of historian Allan Nevins at Columbia University in the 1940's. It was Nevins who first initiated a systematic and disciplined effort to record on tape, to preserve and to make available for future research, individual recollections deemed to be of historical significance.

Historians generally conduct interviews for one of two reasons. To develop an archives of primary source material for future scholarly work or as research for their own scholarly project. A good example of the former is that initiated by Nevins and now continued at Columbia's Oral History Research Office. A good example of the latter are the interviews with former Southern textile mill workers conducted by Professor Jacqueline Hall and her colleagues at the University of North Carolina that resulted in the award winning book Like a Family: The Making of a Southern Cotton Mill World.

There is considerable overlap between these two approaches to oral history, in that scholars conducting interviews for their own research are encouraged to place the completed interviews in an archives or public repository so that others can build upon and also interrogate their research.

Moreover, some scholars do not conduct interviews themselves but draw deeply from extant archival collections. Many historians also use oral history in their teaching, assigning students to interview family members about the Great Depression, for example, or more recently about the 1960's. Historians also use interviews in the production of films, radio programs, museum exhibitions and other sorts of nonprint public forms of historical presentations.

For historians, oral history is a way of getting at information and insights not available elsewhere in the extant record. For many of us, it is also a way to integrate the experiences and voices of the historiographically, if not the historically, silent into our accounts of the past.

I think it is important to state that for historians, oral history is not understood as research on human subjects but rather as research with other human beings. An oral history interview is an interactive process in which the questions of the historian/interviewer elicit the responses of the narrator, which in turn influence the historian's subsequent questions.

Historians view oral history as a unique kind

of primary source. The quality of the interview depends as much on the methodology employed and the relationship between interviewer and narrator, as it does on the significance of the events being recalled and the sharpness of the narrator's memory.

Recognizing the need for sound methodology and professional standards, including attention to the ethics of the unique human relationship that is an interview, in 1968 the Oral History Association, the United States Oral History Association codified, through a lengthy deliberative process, a set of principles and protocols to guide work in oral history. These were expanded in 1979 and revised in 1989/1990, and again in 1998 and 1999, to take into account new concerns and new developments in the field.

This document, commonly referred to as the "Evaluation Guidelines," defines a set of responsibilities interviewers have to narrators, to the public and the profession, and to sponsoring institutions. It seeks to encourage recorded interviews that are as accurate, complete, thoughtful and usable as possible, and to discourage the misuse of oral history.

The American Historical Association, in consultation with the Oral History Association, has

developed a briefer "Statement on Interviewing for Historical Documentation" directed specifically to those using oral history for their own research. I believe you have those -- both of those guidelines.

Which gets me now to 45 CFR 46 and historians' relationships with campus institutional review boards. For years, both OHA and AHA had intermittently been receiving complaints from members who had been experiencing difficulty with their campus IRB's. As a result, in September of 1997, I, as president-elect at that time of the Oral History Association, along with the then president and another colleague, met with Gary Ellis, Thomas Puglisi and Michele Russell-Einhorn of the National Institutes of Health -- National Institute of Health Office for Protection from Research Risk.

The meeting was cordial and informational. We needed to learn more about the federal regulations governing research involving human subjects and the functioning of IRB's. We believed OPRR needed to learn about the professional standards governing historical research, including especially oral history.

At that meeting, Dr. Puglisi stated that the OHA's Evaluation Guidelines are not incompatible with the federal regulations governing human subjects research. Both OHA and AHA guidelines urge those

planning to conduct oral history interviews to meet with potential narrators prior to the interview to discuss the nature of the project, the types of questions interviewers will ask, and the anticipated uses of the collected material.

Both require narrators to sign a legal release form at the conclusion of the interview that addresses copyright, access, identification of narrators, and disposition of tapes and transcripts. Both sets of guidelines specifically advise historians to be "cognizant of and comply with all laws, regulations and institutional policies applicable to their research activities," and further recommend that before beginning any research that may include oral history interviewing, historians should contact their IRB's for policies and regulations governing the use of human subjects in research projects.

In 1997/98 the Oral History Association sent copies of both its own and AHA's guidelines to directors of graduate studies in history and American Studies at universities around the country and apprised them of the need for historians to contact their IRB's prior to undertaking oral history research. You have copies of those or you will get copies of those communications.

Historians do not dispute the importance of high ethical standards governing research that involves human beings, the review of research protocols involving human beings, and the principle of informed consent.

That said, the biomedical and behaviorist frameworks within which 45 CFR 46 was developed have resulted in IRBs' evaluating oral history projects according to standards and protocols not appropriate for historical research, thereby calling into question the underlying assumption of peer review.

This problem is exacerbated by the tendency for IRB's to be composed of people unfamiliar with methods of historical research. Thus, IRBs have asked historians how narrators wold be recruited, when in fact recruitment is not the issue. A request for an interview is based on the potential narrator's sometimes unique relationship to the person or topic under consideration.

We have been asked what the consequences would be if a person refused to consent to an interview. Again, this simply is not an issue in oral history research unless, of course, one considers the consequence of not having a particular person's version of events on record, although, obviously, that is not

what the regulations refer to.

Historians report that they have been told by IRB's to submit detailed questionnaires prior to conducting any interviews, to maintain narrator anonymity on tape and in their published work, and to either destroy their tapes or retain them in their private possession after their research project is completed. Each of these requests misconstrues oral history and violates fundamental standards of historical practice.

An interview is an open-ended inquiry, generally structured around a set of biographical and broadly historical questions. It does not follow a rigid schedule of questions but is shaped by the interview exchange.

While anonymity is an option in oral history and, indeed, quite appropriate in some cases, anonymous sources lack credibility in most historical scholarship. The precise identity of an interviewee often matters as a way of gauging that person's relationship to the topic under discussion and hence assessing the perspective from which he or she speaks.

In fact, most narrators agree to retain their identity in archival collections and published scholarship.

And although narrators can choose to restrict all or a portion of their interviews for a period of time, and sometimes, indeed, interviewers suggest that they do, hoarding or destroying tapes contradicts a primary canon of historical research that sources not only be cited but also be available and accessible as a way of assessing the validity and integrity of the work that draws upon them.

And most incredible to me, some historians report that IRB's have questioned their use of sources in the public record, including newspapers and manuscript collections, as well as properly archived oral history interviews, simply because they deal with the activities of human beings.

Some also question whether the current extensive and often bureaucratically complex review to which proposed oral history research projects are subjected, including even interviews assigned as classroom projects, is, in fact, appropriate for a research activity that generally presents the most minimal of risks to the narrator.

In March of 1998, the Oral History Association, in conjunction with Organization of American Historians and the American Historical Association, corresponded with institutional review

boards at those institutions that had filed multiple project compliances with OPRR. And, again, you will have a copy of this correspondence. This correspondence addressed areas where current review practices seemed at variance with established principles of historical research and recommended that, where feasible, historians be appointed to IRB's.

IRB's were also provided with a copy of OHA's Evaluation Guidelines. In many, perhaps most cases, historians have been able to clarify the issues and negotiate protocols for informed consent and for interviewing that satisfies their IRB's.

And IRB review of oral history research has certainly been facilitated by the recent inclusion of oral history as a category of research that may enjoy an expedited review procedure, something that the historical profession actively advocated. Again that memo in response to the call for comment is also included in the material I have available for you.

Nonetheless, in the spirit of peer review, I suspect many would find it more appropriate for oral history interviewing projects to be reviewed by historians, other scholars in the humanities disciplines, and qualitative researchers among social scientists, according to the terms of OHA's Evaluation

Guidelines.

I think there is a deeper disjunction between the biomedical model of research on which current human subjects regulations are based and the research that historians and perhaps those in other humanities and social science disciplines engage in.

This lack of fit is suggested by reports by some historians that they are requested by their IRB not to ask questions about certain sensitive subjects, such as an individual's criminal history or history of arrests, thereby obviating a lot of research on the civil rights movement, for example. It is suggested by the current regulation that, where appropriate, a statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject. It is suggested by the need to identify the risks or discomforts an interviewee may experience during the course of an interview.

In all of this there is the possibility, or perhaps even the hint, that, according to current regulations, controversial, difficult, or challenging topics cannot be addressed in historical research.

The need to treat individual narrators with

honesty and respect is not the issue here nor is the need to apprise them of the nature and purpose of any interview. What is at issue is the notion of critical inquiry, inquiry that does challenge, that may be adversarial, that may even expose, as interviews with Klansman and women and with Nazi collaborators, for example, have done.

Yet current regulations, interpreted narrowly, can have a chilling effect on historian's freedom to pursue these difficult topics. Moreover, historians pursuing research on some 20th Century topics may find they have acquired critical, if controversial information with profound consequences for public life. They may further determine that the public's need to know may have greater urgency than may be allowed for in current regulations.

The boundaries of current regulations are admittedly unclear about these sorts of issues but I think it is fair to say that historians believe it is imperative that they not be used to hinder the recording of our recent past.

Thank you.

DR. SHAPIRO: Thank you very much. I appreciate your remarks, as I do for all members of the panel. Let's now just go to questions from

commissioners.

Alta and then Tom.

DISCUSSION WITH COMMISSIONERS

MS. CHARO: Thank you, all, for vivid and concrete presentations that raise some very specific examples in my mind at least. The question I have is probably directed most to Ms. Shopes and Dr. Wax, although I am interested in all of your responses.

It has to do with a potential alternative to the conceptualization of which activities ought to be given special kinds of review in which one focused -- and this is not because we are going this way but it is a potential.

One focuses less on whether what one is doing is a systematic investigation for generalizable data and more on the notion of the relationship between the so-called investigator and the so-called subject and focuses on whether there is any possibility for a situation in which the subject is now merely a means to somebody else's ends and further whether that raises specific risks.

The kinds of risks that it can raise are a chance of confusion in which I believe that there is a fiduciary responsibility to look at for my interest but, in fact, that is not present or is secondary to

some other purpose. Or a chance of ignorance in which I fail to imagine the kinds of risks that this involvement poses.

I mean, in the chance of confusion obviously I will fail to self-protect because I am assuming you are protecting my interests. Chances of ignorance, I might fail to perceive risks and, in fact, Ms. Shopes your final comments raised this specifically. I may fail to perceive the risks associated with revealing information that could render me vulnerable to prosecution because the statute of limitations has not run for the kinds of things I am discussing with you.

I am very interested in the two settings you have described because you speak with people so long and in some cases live with people so long that I am finding myself wondering if personal relationships develop that raise the question of confusion about roles even though at the outside it is quite clear to everybody this is a research project but nonetheless in an evolving fashion, confusion about the relationship with the investigator can occur, and second whether in your experience the ignorance issue is one that is significant because this would suggest -- this would be informative as to whether or not it is possible to try and divvy up the world along these lines of

relationships that ask where do we need third party protections and where do we not.

DR. SHAPIRO: Yes, Professor Wax?

DR. WAX: Thank you for the very informative questions.

Yes, first of all, communicating to another group of people who are culturally different about what we are doing is extremely difficult and what happens really is that a relationship develops or fails to develop and the relationship is subject to all the kinds of things that social relationships do.

I was privileged to participate in a project that asked a sample of Indian communities, American Indian communities, how they felt about the research that had been conducted amongst them in the past 20 years, not just anthropological research but research generally, and their responses were so different than we had anticipated because they focused not on let's say medical care or the quality of it but upon the relationships that had developed or failed to develop, and the concern or lack of concern they felt with the investigators. They tended to look completely jaundiced about the purpose of the investigator. They did not believe it.

When I did research -- first did research

among the Ogdala Sioux they could not believe that I was really there to study children in schools. They thought, well, I am a social worker, I am an FBI agent, I am all sorts of other things, and no matter what I said for the first three months, they did not believe it. And if I were they, I would not have believed it either.

Moreover, if I had given them a piece of paper to sign they would have withdrawn all. They would not have talked to me ever because from their point of view any piece of paper threatens their claim on the Black Hills and the government has given them all sorts of pieces of paper in the 19th Century that made for irredeemable losses. So they would not have done that. They had to judge me as a person.

And, as I say, you know, anthropologists are no more moral than anybody else but if you are there within a community you find yourself subject to all the rules and regulations of that community or you are in bad trouble.

That is -- so, yes, information through the cultural lines of difference is -- just does not filter very well. My own proposal and I will jump ahead for a moment is that what we are doing is we are looking too much at the onset of research and too little at what

happened to the research itself that we are asking a researcher to predict what he or she is going to be doing and how it will affect the people defined as subjects, and we are not looking afterward to see what, in fact, happened and how do various people feel about what happened.

My own feeling -- by the way, I must say that I am utterly skeptical about IRB's and informed consent because my vision of informed consent, which is very personal, is being -- but just before a major operation being given a sheet of paper by the anesthesiologist asking whether my permission to use various levels of anesthesia. And I thought to myself this guy has my life in his hands and I do not even have my eyeglasses on, you know. And he did not ask. He did not come by a month later and ask me where I was, how I felt, and what were the after effects.

So my feeling is that we are concentrating up front not on what happened and how people feel about it.

My own feeling is, yes, anthropologists tend to be, you know -- novice anthropologists tend to be like Joan Sieber pointed out. These people are 100 or 300 research subjects and they are going to -- these are nice people who are going to give me my Ph.D. by

answering my questions.

You try living there for a year among these nice people and you will find out that they are very effective in protecting themselves from your inquiries. That does not mean that you cannot exploit them but the exploitation often is quite mutual and they are usually -- you know, especially with American Indians. These people have seen people come and go and come and go and they are very gifted at getting things out of you. That does not mean that they are not justified. It just means that life is very complex.

And now Dr. Shopes.

MS. SHOPES: Yes, if I understand you correctly, you are suggesting protections from a confusion of roles and a narrator's ignorance really of the purpose of what they are talking about.

MS. CHARO: Basically, one could try to reconfigure what gets regulated or what gets special review based on something.

MS. SHOPES: Yes. You know, those are interesting and useful possibilities to think about. I have two immediate concerns. One is that such an approach would not prevent historians from interpreting the results of their research in ways that the human subjects, if you will, would not necessarily agree

with.

I think that would be a real problem for historians to simply take at face value what they hear. I also would be concerned that -- and I will give you an example here -- that some people's wilful ignorance, if you will, cannot be appropriately addressed and I am thinking of research actually by a historical sociologist on women who were members of the klan in the 1920's in Indian.

Are you familiar with that? Yes. You know, then I do not need to really be too terribly specific except that these klanswomen that she interviewed simply could not understand how she could take a critical approach to the klan. For them it was everyday life. And that failure to comprehend that she might have a different point of view allowed them to be quite open.

Now I just checked this book out because I wanted to see how she handled some of these issues and it could be quite damning for some for these narrators to be presented in this book with, indeed, quite -- what I would consider quite damning information.

She did maintain their anonymity. A question arose for me, however, perhaps even the name of the individual person in this case did not really matter.

You know, their individual identity is not important to the story that she is trying to tell but what if she were doing another kind of research and it was evident that certain important people in the community, bankers, church men, were members of the Klan, and n positions of power exercised a certain kind of social control. Would it be appropriate to maintain the anonymity of those people? Or would it even be possible given the fact that they were public figures and you would not even have to use their name but historians do not write about fictive places. They write about real places and real time. People would know who those people were.

So, you know, those would be some of -- I think perhaps implications of the procedures that you are suggesting although it would lead to some interesting conversations, I think, too.

DR. SHAPIRO: Thank you.

Tom?

DR. MURRAY: Thank you, Harold.

And thank you to the four panelists very much.

I guess what I am about to engage in is a brief -- probably moral history rather than oral history. I want to think about the sources of our concern and the ways which we have articulating them.

And I am especially struck by the -- what appears to me to be a contrast between Professor Wax and Ms. Shopes, it is a take on the relationship between subject and researcher, and Professor Sieber at least in so far as it concerns deception research paradigms.

The history I wanted to take is if you look back at the most influential sources, some of the most influential sources on the ethics of human subjects research you go back to people like Paul Ramsey who wrote about the concept of co-adventurer, the subject as co-adventurer in the research project with the investigator.

If you look back at Hans Jonas who talked about the need to -- not to conscript people in the name of science but rather again to respect their dignity and enlist them, if you will, voluntarily in it.

And if you look at the methodologies and ethnography and oral history you see by and large a very straight forward relationship. I mean, not simple, complicated in all the ways you described and potentially perilous for the subject but also sometimes for the researcher but out there.

I am an anthropologist and I have come to do a study. I am an historian and I have come to talk to

you about something that we find interesting.

It picks up a distinction philosophers make, Steve Holtzman alluded to it earlier, between harming and wronging, which I think is incorporated into -- informed consent is, I think, intended to both prevent harm, the idea there being if you tell people we are going to do something very dangerous to you they say no so it helps prevent harm but even more so it provides -- it respects the dignity of the individual and says we are calling on you in the name of science. We want to enlist you in this project as a co-adventurer. Do you agree to do that or not?

If you take that -- that is a fairly crisp view. If you take that view that really -- if you take it to its logical conclusion it would completely eliminate research that deceived people about being engaged in research or about any of the significant elements of the research protocol.

Joan Sieber probably knows my history here, which is 30 years ago I started raising these questions about deception research in a department of psychology, got mainly head scratches and puzzled stares, and later on hostility. Not in that department but among others to whom I based these questions.

I wonder if anything has changed in 30 years

or is the deception paradigm essentially untouched. What I believe I have found in those days was an insensitivity, if you will, a kind of tone deafness to the notion of wronging that one might be wrong by being involved in research, and even Alice Eisen's study, which is cute, those people, I take it, did not know they were involved in an investigation and so you get a -- you end up on a continuum.

I know of other studies where accidents were staged and people had no idea -- they were just staged in public and people had no idea whether they were -- that there was an experiment but they, in fact -- they were being observed.

So I wonder, Joan, if you could tell us where things are now 30 years later?

DR. SIEBER: Well, the answer is that there is a great deal of variability. I was quite astounded to discover in reviewing the articles in the Journal of Social and Personality over the last 30 years, a couple of my students and I went through and coded articles on the kinds of endeavors, the percentage of deception, the kinds of deception, the areas in which they occurred.

And what we found was that the nature of the deception has changed quite a lot. There was a period

when there was much -- when people stopped researching sensitive topics where deception was needed. In other words, the regs had really had a very chilling effect on certain sensitive areas.

More recently there has been an increase again almost up to the prior level in percentage of articles in that journal. Now, of course, that is the journal to look for deception studies so it is certainly not representative of the whole field.

The kind of thing that has happened increasingly, though, and unfortunately the journal articles were not highly informative on what the consent procedure was but I do know that in most of the kinds of experimental studies that JPSP publishes, which are done in academe with college students that they ask the students would you be willing to participate if we do not tell you everything at the outset and then debrief you. And so that the informed consent is, "Sure, I will play that game."

So I would say that there has been an impact. I would say there is -- that the impact actually had a chilling effect on certain sensitive areas of research and I think that people are very gun shy about doing things that people would be ashamed of having participated in.

We are learning how to use somewhat more acceptable practices in those areas where some concealment is necessary. I guess that is the best answer I can give to a whole diverse set of events.

DR. SHAPIRO: Thank you. Professor Wax, did you have a response?

DR. WAX: I just wanted to add one other proviso. When I did our first study among the Ogdala Sioux on children in school, after the study was over we wrote up a monographic report and sent copies back to the Sioux. Then we heard via the grapevine two kinds of responses. One was the Sioux equivalent of you have scored a major coup. The second was if we had known that is what you really going to do we might have helped you. And this --

(Laughter.)

DR. WAX: I also want to say that one of the most elusive people to try to interview turned out to be the Sioux teenagers. They were wonderfully gifted at nonresponse.

(Laughter.)

DR. SHAPIRO: Okay. I have quite a few of my colleagues who would like to speak and I hope we have time to recognize them all so let's be as brief as possible.

Jim?

DR. CHILDRESS: Thanks very much. Professor Wax and Ms. Shopes, you dramatically identified some problems with IRB's in the areas of research that you are concerned with and I guess my question really concerns what you think about how pervasive and widespread those problems are, whether you have reports, anecdotal or more systematic reports of IRB's being educated to interpret the regulations in a way that would permit the research without the kinds of burdens you have indicated and whether you have any suggestions for how investigators and others might go about educating IRB's and would hope IRB's educating institutions since we have heard today that some of the pressures arise from within the institution for IRB's to be as conservative as possible.

So any reflections you had along those lines would be helpful.

DR. WAX: Well, on the one hand, I am a great believer in casuistry. That is to say I am a great believer that abstract principles, ethical principles are very good, but we also need to see where harms and wrongs are being done, and we do not know really enough about that so as to really make that connection between the two.

And I wish somehow there were in the whole system a much more research going about IRB's and their impact on research. What we have here is what an anthropologist would do. That is narratives from people as to what they have observed.

I can say from what I have been hearing here that the pressure seems to be that IRB's are rewarded for being risk aversive and not rewarded for being adventurous and that the government operates with an iron club rather than education. In the case of the American Anthropological Association we have finally realized that we did not have the funds and people to really monitor accusations and that was a blessing because we then turned to the notion that what we had to do was educate researchers and prepare them for what they might encounter, and have a forum for discussion of troublesome issues.

And that, I think, has been on the whole useful but as I say I think it would be very interesting to do more research on the experience of investigators with IRB's and federal regs.

Thank you.

DR. SHAPIRO: Ms. Shopes?

MS. SHOPES: Yes. Let me try and answer your questions. I think it is hard to tell how widespread

the problem is. I have anecdotal evidence that surfaces on the oral history listserv quite regularly that I would certainly be happy to provide you with but there is no way of gauging how extensive this is.

I did mention this to Dr. Speers. The American Association of University Professors has convened a working group of representatives of professional associations in humanities and social science disciplines to look at this issue of IRB review of our research and as a result is currently engaged in a process of surveying -- the different associations are engaged in a process of surveying their members.

The survey for the American Historical Association, which body I represent on that working group, has just closed, if you will, the survey period.

I reviewed perhaps 50 responses that we received from a survey that was sent to the entire membership of 9,000, speaking roughly. Very interesting information and very interesting data. Again I would be happy to share that with you.

I do not know how accurate this is as a gauge of how widespread you hear the complaints but we also have heard some -- you asked for examples of good relations between history programs and IRB's. Yes,

there are some.

I think everyone finds it fairly a nuisance, that the process is too cumbersome. I think many appreciate the value and there have been -- particularly for oral history programs -- university based oral history programs as at Columbia, at UCLA, at the University of Nevada, Reno and others, they have developed cordial relations with their IRB's and have a very expedited review process. So there are those relationships that are in place.

Recommendations: I cannot speak for the profession here. I do not think or I know we have not come to the point of being able to formally make recommendations. Perhaps we will be able to in coming months. I think a codification of good practices would be in order that would be disseminated to history departments, history programs, and institutional review boards.

I think a reliance on the professional standards that are already in place developed by the American Historical Association and the Oral History Association and perhaps they need to be revised and reviewed in light of IRB and Code of Federal Regulation concerns. I think it would be appropriate to take a look at those.

A lower level review at the departmental level. I do know of a couple of cases where that has been institutionalized within history departments through good relations with their campus IRB's. They basically do the review of oral history projects at the department level.

So if that answers your question.

DR. SHAPIRO: Thank you.

Diane?

DR. SCOTT-JONES: Some aspects of my question have already come up but I will just go through it anyway. As all of you were talking about your different fields I tried to think what would it take to remedy some of the situations you brought up that were not exactly to your liking and I came up with six areas. I will just go through them and ask you if you could respond to them.

The first one possibility might be different and separate IRB's from those that review biomedical research and Ms. Shopes just mentioned the possibility of review at the departmental level rather than the university level.

A second would be different and separate regulations from those that are for biomedical research.

And then a third would be a greater reliance on professional societies and their regulations or standards, presumably they are closer to the specific disciplines.

Then, fourth, there is a possibility of different procedures. An example would be instead of written informed consent, tape recording or having an independent person document that consent, informed consent was given.

Then, fifth, monitoring ongoing projects and then at the conclusion of the project, reviewing the project for whether it met ethical standards.

And then, finally, no review of research in your areas for ethical standards.

Do you have any response to what ways we could go of the things that were hinted at or mentioned directly in your talks?

DR. SHAPIRO: Please choose your favorites amongst that list because if each of you deal with six we will be here a long time.

DR. SIEBER: I would like to respond to Diane's question about local review and education.

There is an issue that Diane and I are both very sensitive to, having been on a committee that wrote a lot of friendly guidelines on how -- on best

practices, which one governing -- one society refused to have anything to do with because we might be thought of as prescriptive. And which the other body went through and edited out anything that even resembled the word "should."

It certainly reminded us that education and enforcement need to be very separate or you get professional societies that are very risk averse. If we say you should do something then they are going to come after us if we do not.

And yet what we have seen from this panel is that a great deal of flexibility is needed given the different areas of research. It seems to me that because this is going to be an issue for a long time -- I mean, Murray and I have known each other for 25 years. There will be another 25. We need to focus on educating undergraduates.

It seems to me that there is tremendous importance to putting out useful principles of best practices and putting them where you do not have to depend on a professor or buy a textbook. It is called the internet. And I think it is the perfect defense against overzealous IRB's and it is the way that the people at the lowest levels in the food chain can get the information that they need to perform research

ethically.

DR. SHAPIRO: Thank you. Any other comments or responses?

MS. SHOPES: Yes, just briefly. I think that my personal preference would be greater reliance on professional associations and the professional standards that have been developed within the disciplines. I think those two work quite well together.

And then, as I suggested, a review at the disciplinary level.

DR. SHAPIRO: Just to say a word about that because it occurred to me as I was listening to people talk. I understand -- of course, it is easy to understand why review standards by professional organizations would have a lot of quality to it, they understand the discipline best and so on and so forth. I can well understand all that.

At the same time it would be very useful to have societies tell us what restraints they might suggest. I mean, I understand everybody wants to do everything they want to do and they object to anything that gets in the way but I mean the whole idea here is that in some cases values have to discipline interests. I understand the interests of economists or historians

or others.

It is sort of annoying to have something in the way. I understand that very well but on the other hand we do have to look to the professional societies not simply to help themselves out but to tell us what disciplines they think should have and then we would have sort of a credible way to look to the professional societies to help us out in this area.

So it has to be both sides of this, it seems to me, as we might go down that road. I am sorry. That is just a gratuitous comment but in any case, I think that is really quite important.

Okay. Any other responses?

Yes?

DR. ABOWD: I just wanted to thank you because I do really need to go back to the Census Bureau.

DR. SHAPIRO: I apologize. I appreciate it. Thank you and thank you very much for coming. I very much appreciate it.

DR. COX: Mr. Chairman, can I follow-up to your gratuitous comment?

DR. SHAPIRO: Yes.

DR. COX: I know it is out of order and that is that if the professional societies -- okay. Because each of you have said, right, that you would not be

here if you did not believe in doing research that was ethical and that implies to me that there are situations where the interests of the individual trump the interests of the research. Is that correct?

I mean, we do not have to define what they are but is it -- well, so is it ever the situation where that the interests of the person that you are talking to -- in the case, I do not -- so in the case of a historical interview. All right. That they trump the importance of the research itself because if it that is not the case, I have a real problem because then it is what Harold says. It is that the scientific discipline always trumps.

So what is the answer do you think? Because if it is the case that the scientific discipline always trumps and I will tell you in my own personal scientific discipline, right, which is a biomedical one that the -- I will not say the majority but a large number of my colleagues, the discipline always trumps, and that is why I have a big problem. So I do not know what the situation is in history or in anthropology or in psychology.

DR. SHAPIRO: Professor Wax?

DR. WAX: It is not that I would disagree with that. First of all, in responding to your comment, I

would say, yes, I would be in favor of the professional association doing the monitoring. However, what I have found is that the complaints that come to the professional association are mostly of colleagues versus colleagues and we have never been in a position where let's say an aggrieved American Indian came to the association.

Instead what we now have, which is much better, is somebody like Vine Didoria (phonetic) writing a book that became very famous, Custer Died for your Sins, about being afflicted with anthropologists. What he really meant since he is a good friend of mine -- I can -- he once confided to me that the real problem was that when he was executive chair of the National Congress of American Indians he was operating in an office that was absolutely poverty stricken and researchers would come to him, who knew nothing about Indians but wanted the name and address of the Tribe they were going to research, or similar kinds of information.

Anyway, Vine wrote a series of brilliant essays. Our problem is that we -- unless there is some mechanism to elicit from the subject people we do not really know how they felt except retrospectively, you know, in the case I told you where they said, "Oh, if

you were going to do that, if we had known, we might have helped you."

So it is not that I am saying that anthropologists are particularly moral and it is not even disciplinary interest. It is, you know, how am I going to get the Ph.D. or the monograph or whatever else.

What does tend to regulate is that people will not cooperate with you unless they sense that you are interested in them and very often then they will come to you and insist that you hear their story. That is the optimal case.

But, yes, you are absolutely right. Disciplinary interests do tend to trump concern about ethics and that is why I am arguing for what I call post-hoc briefing or debriefing but that is the best I can come up with at the moment.

MS. SHOPES: Let me try and address --

DR. SHAPIRO: We have one more question -- after this we will have one more question from Steve and then we have to adjourn.

MS. SHOPES: Okay. Let me try and address this. I mean, on some level the interests of the individual subject trump the researcher when they refuse to be interviewed but I suspect that is not what

you are speaking of. And, yes, theoretically, I would say, of course. I cannot think of a specific example where you in advance or a peer review process in advance would determine that this person or this group are so vulnerable that you would not interview them but that does not mean that, theoretically, it would not be correct.

Quite frequently in the kind of research I am familiar with, topics trump the researcher. It is quite within accepted practice prior to an oral history interview to discuss the topics and be quite clear are there certain topics that are off limits. So in that sense I think it is already codified within accepted practice.

DR. SHAPIRO: Thank you. Steve?

DR. HOLTZMAN: Thank you. When I was reading the material sent out last night to us there was a proposition in front of us that instead of trying to come up with a definition of research, what the commission ought to do was focus on the question of what should IRB's regulate and that will give us a different kind of approach.

And as I sat and listened to the incredible diversity of things where there is the potential for harm, it really got me thinking about what it is we

should be thinking about even under an approach of what should an IRB regulate.

So I found myself writing down that, you know, last week I went to my local drug store, the OSCO, and swiped my little discount card with my bar code on it and so, of course, now the OSCO knows exactly what I bought, probably knows things about my personal habits that none of you want to know about. Who controls the reuse, the resale, the research use, the protection from junk mail and junk phone calls that will eventuate from that information?

And as I listened to these issues of social science research, it seems pretty tame in terms of the potential harms, okay, compared to what goes on a matter of commerce, which we do not think of as research. And I have made the point.

I actually remember in the biological materials context last summer that for people like myself who are officers of publicly traded companies, you can go on the net and you can find out my net worth. And when people do that, they do things like steal my identity and whatnot under law. Right?

So I think it brings back to us the question, what do we really care about and what do we want to focus on? Do we want to focus on a biomedical

paradigm?

And it raises further questions that came up at the last conference of what is this special relationship between a subject and say a doctor that is the cause of how we think about -- what I call demeaning or symbolic content of that relationship that puts in place a necessary framework, which could be distinct for the different kinds of relationships that exist between the kinds of research you do, and you is various, to those subjects.

It is just a set of thoughts.

DR. SHAPIRO: We will have lots of time to discuss that this afternoon.

So let me call this part of our session together. Before we adjourn, I do want to remind the commission that we have public comments at 1:45 so we ought to be back here as close to 1:45 as possible just with respect to people who have come for public comments.

Finally, let me thank our panel once again. I very much appreciate you taking the time to be here and we value -- benefitted a lot from your testimony.

Thank you very much.

(Whereupon, at 12:55 p.m., a luncheon recess was taken.)

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A F T E R N O O N S E S S I O N

DR. SHAPIRO: Colleagues, I would like to call our meeting to order, please.

Diane, Bette, Arturo, let's go.

Colleagues, I would like to call this afternoon's session to order.

PUBLIC COMMENT

DR. SHAPIRO: We did have two individuals from the United Methodist Church who had signed up for public comment. I do not believe they are here but let me just check.

Mr. Corey Kinna and Brian Haines.

Are either of them here?

Thank you.

Is there anyone who is here that would like to address the commission at this time?

(No response.)

DR. SHAPIRO: All right. Then we will go ahead with the other aspects of our agenda for now.

There are -- we are going to focus our attention this afternoon on really two issues which are summarized in the agenda as recommendations regarding the definition of research, which we will come to in a moment and have a good deal more to say about that and we will have adequate time, I hope, to discuss it

fully.

And then we want to get an update on the result of our survey of federal agencies. Those are really the two issues before us this afternoon.

And Marjorie has also developed some materials which were requested by the commission regarding just information regarding the structure of regulations and so on and she would like to speak about those and there are some additional materials at your place that relate to that.

That is the package of materials that look like this on the front of it. I think everybody has that in front of them and so let me turn to Marjorie to deal with that first.

DISCUSSION WITH COMMISSIONERS

DRAFT RECOMMENDATIONS ON DEFINITION OF RESEARCH

DR. SPEERS: Thank you.

I have asked Stu Kim to operate the overheads and that is by way of telling you that Stu Kim worked with me on this project.

In response to really your request to better understand what the current regulatory structure is we have tried to develop some visual aids for you that will help you understand the current structure fairly quickly and readily.

(Slide.)

The first overhead basically describes for you the signatories to the Common Rule on the left hand side. This is the -- this includes the agencies who signed the Federal Policy for the Protection of Human Subjects in 1991 and also includes the two agencies that follow the recommendations or the federal policy but were not signatories at the time, and that was the Social Security Administration and the Central Intelligence Agency.

We also had listed on the bottom the Office of Science and Technology Policy because they were a signatory to the Common Rule but they have no regulatory responsibility and, therefore, did not codify it in regulation.

So when we speak bout the signatories to the Common Rule we are generally referring to 18 departments or agencies within the Federal Government that follow some form of the Common Rule.

On the right hand side what we have listed are the federal agencies that are not signatories to the Common Rule and that is what it says. It does not mean that all of them conduct research and are not signatories. It simply means that they are not signatories.

We do believe that some of those agencies are either engaged in research or fund research. That is that they sponsor research even though they are not signatories to the Common Rule.

(Slide.)

The next chart that you have on the overhead -- this is a graphic representation of the current regulatory system. We have color coded it to help you very quickly understand what the current structure is and let me just walk you through it.

We start on the left-hand side with the Federal Policy for the Protection of Human Subjects, which is also known as the Common Rule, and to remind you that the Common Rule is 45 CFR 46, Subpart A only. That is what is referred to in the federal policy.

We use the color blue or almost a baby blue to indicate to you that it is a policy. It is not regulation so it does not carry the force of law that regulation carries. It is a policy and you may recall that Michele Russell-Einhorn mentioned that in her presentation last month to the commission.

The dotted lines out to the federal agencies represent the agencies that, as I say, were signatories to the Common Rule or the Federal Policy in 1991. Those agencies codified the Federal Policy in

regulation and what we have given for you in this chart is the Code of Federal Regulations where it is codified for each of those federal agencies.

From some of the federal agencies you see boxes that included additional regulations that those agencies. They are either regulations or --

(Telephone interruption.)

DR. SHAPIRO: Sorry.

DR. SPEERS: That is okay.

So the boxes include, as I say, additional regulations or policies that carry the force of law that have been adopted by these respective agencies. So, for example, you see under the Department of Health and Human Services 45 CFR 46, Subparts B, C and D, which are the additional protections for vulnerable populations. Under the Department of Justice it includes regulations related to research involving prisoners. Under the Department of Veterans Affairs it is their regulations regarding compensation for research injuries and so forth.

We have connected in this table the Social Security Administration and the Central Intelligence Agency to the Department of Health and Human Services because the public law that created the Social Security Administration included specific language that requires

the Social Security Administration to follow the regulations of DHHS so that the Social Security Administration's regulatory authority, if you will, comes from that public law and then connects it to DHHS regulations.

The same is true with the Central Intelligence Agency. Executive Order 12333 has specific language in it that connects the Central Intelligence Agency to the regulations and guidance for protection of human subjects that the Department of Health and Human Services have.

So I want to clearly point out is that those two agencies have the additional protections that are under 45 CFR 46 because of their statutory language.

We listed in this table the Food and Drug Administration out to the side and we did that because we wanted to point out a couple of things to you. One is that the Food and Drug Administration is an agency within the Department of Health and Human Services so it is not a separate department as the others are.

However, it is an agency that has its own set of regulations, you know, and it is a separate set. It is separate from the Federal Policy for the Protection of Human Subjects so we have listed it there so that you can see how it fits into the structure.

I hope that this diagram gives you the information that you want and that it will be useful to you in our future meetings when we return to the topic of alternative models. The plan would be that we would have this chart available and then we could look at alternative models to the current models and you would see how changes in the structure could potentially affect regulatory authority and rule making processes.

(Slide.)

In the next chart that we have given to you this essentially lets you ask the question, well, what does this regulatory structure mean from the consumer's point of view if the consumer is the IRB. And so we have two case examples here for you. One is an institution with a multiple project assurance from the Department of Health and Services, and then in the next chart, which we do not want to put up yet, is an example where an institution does not have a multiple project assurance and all we have listed here for you are some examples.

So, for example, if an institution receives funding from the National Institutes of Health, the IRB would follow 45 CFR 46. If the institution receives or is conducting research that is regulated by the Food

and Drug Administration and it has a multiple project assurance, it then is obligated to follow 45 CFR 46 as well as the two sets of FDA regulations, 21 CFR 50 and 56.

If the institution receives funding from the Department of Education, and I just picked another department to make the case, then again they have to follow 45 CFR 46 as well as the applicable regulations from the Department of Education.

And, finally, if an institution with a multiple project assurance receives funding from the private sector, if that multiple project assurance obligates the institution to cover all of its research then it would follow 45 CFR 46 but it is possible for an institution to have a multiple project assurance where in that assurance it does not obligate the institution to review all of its research according to the federal protections.

Yes?

DR. LO: A question. How many institutions that have an MPA are not required to apply the Common Rule to all the projects in the organization? Do you have any sense of that?

DR. SPEERS: No. I do not have any sense -- that would be a question that we would have to pose to

the Office for Protection from Research Risks and try to get an estimate from them of how many institutions we are talking about in that category.

DR. HOLTZMAN: Marjorie?

DR. SPEERS: Yes.

DR. HOLTZMAN: Because your left-hand column here includes both funding as well as regulatory, it is probably worth noting that for the private sector stuff, the overwhelming majority of which is pursuant to an FDA IND, if you are at a place with an MPA, the FDA regs would also be controlling so you would have all three.

DR. SPEERS: Yes. That is certainly true for the FDA regulated research. We were -- but again just to make the -- yes, just to make the point, though, that there are a number of organizations that fund research from the private sector where it would not fall into that category.

(Slide.)

And then in the other case when an institution does not have a multiple project assurance, just very quickly to go through this one for you, again if it were the National Institutes of Health that were funding the research, yes, a single project assurance would be required and 45 CFR 46 would be followed.

If it is FDA regulated research there would be no requirement for a single project assurance from the Department of Health and Human Services, the FDA regulations would be followed.

For the Department of Education there would not be a requirement for a single project assurance from HHS but the Department of Education issues its own assurances and might do that and then the Department of Education regulations would be followed.

Another example is the Department of Defense. An HHS assurance would not be required. The Department of Defense would issue its own assurance.

Yes?

MS. CHARO: For the Education and Defense listings you say that they may obtain an SPA from that department. Is that because it is not required that they get an SPA from those departments? And if that is the case, why would they ever want to bother with one?

DR. SPEERS: The Department of Education is here and so let me let them answer the question.

This is for the record Eileen Deramond from the Department of Education.

MS. DERAMOND: The Department of Education requires a single project assurance if the institution is receiving funding -- Department of Education funds

and does not have a multiple project assurance.

MS. CHARO: Okay. So that, in fact, we could read the chart to say the institution must obtain an SPA from the Department of Education?

MS. DERAMOND: Yes.

MS. CHARO: Okay. Thanks.

DR. SPEERS: And I know from talking with the Department of Defense it would be the same so we will change that.

MS. CHARO: Thank you.

DR. SPEERS: Okay.

(Slide.)

And, finally, in this chart, again just to make the point with the private sector that if this were funded by the private sector there would not be a requirement for a single project assurance and there would not necessarily be any regulation that had to be followed.

(Slide.)

The last handout in your packet and overhead is not a chart that we developed. This is one that Gary Ellis from the Office for Protection from Research Risk has developed and used often in congressional testimony.

It is a slightly different type of chart where

what he is representing using various circles is the human -- all the human subjects, if we have the universe here, the largest circle being the universe of human subjects or individuals who participate in research, is to show that through the Food and Drug Administration regulations or through the Common Rule many subjects or individuals benefit from federal protections but, in fact, there is some universe which we are not able to define of individuals who do not benefit from the federal protections.

Yes?

DR. DUMAS: In the case of the private sector, if there are private sector funds in an institution that also receives public sector funds does this change whether or not they need project assurance?

DR. SPEERS: It -- the answer to that question is it depends on the commitment that the agency has made through its multiple project assurance.

DR. DUMAS: To the institution.

DR. SPEERS: To OPRR and that is again -- when you say public sector funds we are talking about HHS funds.

DR. DUMAS: Right.

DR. SPEERS: If an institution receives HHS funds and has a multiple project assurance then it

depends on what that assurance says, what commitment the institution has made, to either review only federally funded research or to fund all research.

DR. DUMAS: Or all research. Okay. Thank you.

DR. SHAPIRO: Alta?

MS. CHARO: This is a bit tangential but since you have mentioned OPRR several times, I wonder if you can tell us your latest information about the status of the change of regulatory authority from OPRR within NIH to an office within the Office of the Secretary. I understand that the people involved in regulation of animal research have already made the move, the people overseeing human subjects research are in the midst of the transition but I wondered if you could tell us exactly what the status is now.

DR. SPEERS: I will do that unless Paul Goebel, who is representing OPRR, would prefer to it.

DR. GOEBEL: You may have better information than I do.

(Laughter.)

DR. SPEERS: Do you want to tell us what you know and then what I will do is --

DR. SHAPIRO: And we will tell you if you are right.

(Laughter.)

DR. GOEBEL: That should be interesting.

The animal people are in the process of moving out. When I was at 6100 Executive Boulevard yesterday there were still boxes in the hall to be packed so I am not sure whether they are out or not.

The time table that I heard is that some time before October there is -- a new director will be chosen or a director from the advertisement will be chosen, whether it is someone new or not, I do not know, but a director will be chosen and the OPRR will move to HHS. I am not sure if there is -- if one is supposed to happen first or if they are each on an independent time table but the last I heard is some time in October.

We were scheduled to move physically. That now has been put on hold because the previous deal fell through so that again is indefinite.

DR. SPEERS: I really do not have more to add in terms of what we know that -- I guess the only thing I would add is that I understand that either very -- very soon a notice is to go into the Federal Register making it known that the animal piece and the human piece are splitting apart and that the OPRR will be moving from the National Institutes of Health into the

Department of Health and Human Services.

DR. HOLTZMAN: Thank you.

DR. SHAPIRO: Thank you. Any other questions for Marjorie regarding this material?

Well, thank you very much for putting it together. I think it will be helpful.

Oh, I am sorry. I did not see your hand. I am sorry, Tom.

DR. MURRAY: Marjorie, I suspect I speak for man of the commissioners to say that this is a superb rendering and the clearest description, certainly this chart with the red and blue and black, I have ever seen of the situation so thank you.

DR. SPEERS: Well, thank you. Really we need to express the thanks to Stu Kim, who did the creative work to figure out the best way to present this so that you could understand it in 15 minutes or less.

DR. SHAPIRO: With this commission that is -- we will not have any examinations quickly. Okay. Again, also, my own thanks, Marjorie, to you and Stuart for getting this together.

We now want to move on to the discussion of what were called draft recommendations of a particular aspect of our forthcoming report. This was all distributed to you and surrounds the issue of when

federal regulations or review gets instigated and what the criteria are.

This was all distributed to you, I think, certainly before this meeting and we have already had some responses to it but let me turn, first of all, before we begin our own discussion to Marjorie to initiate discussion and then we will see what issues are on commissioners' minds.

Marjorie?

DR. SPEERS: Thank you. I will just give you a little bit of background and the thinking that went into developing this draft recommendation for you to consider today. Through the discussions that we have had to date and actually in anticipating what you would hear today, this recommendation was developed. It is based on several themes and I am just going to go quickly go over those themes even though they were in the memo that you received.

One is that for some areas the current definition of research is problematic because it is difficult to determine whether an activity is research or nonresearch. And I think, as you have heard in testimony, we are very often not talking about the extremes, we are talking about the margins, we are talking about a gray area, and I think that that gray

area is larger or smaller depending on the discipline that we are discussing.

The current definition of research does not cover all the activities that should be reviewed by an IRB, we have heard that there are other types of activities that would benefit from an ethics review or a review from an institutional review board, and moreover that the current definition of research probably cannot be revised so that it encompasses all of the activities that should be reviewed, and that perhaps a more productive approach would be to try to define categories of activities that should come under the federal regulations and be reviewed by an institutional review board.

This recommendation was set up with a couple of thoughts in mind. One was that the commission -- that you will need to consider several other areas and make perhaps additional recommendations. What I mean by that is that we will also need to discuss the definition of a human subject. We will need to discuss the exemptions and different types of review so that, you know, we are sort of stabbing into this process but you need to keep the full process in mind and we may have to come back and look at this again after we have made some of the other decisions.

Secondly is it parallels in some ways the regulations now and follows the -- potentially could follow the decision making process that occurs in the federal regulations, which is the first step is to decide whether it is research or nonresearch or what would be changing to is, is this covered or not covered, does it involve human subjects or not, and then is it exempt from review or not exempt so this was set up with that kind of decision making in mind.

The recommendation really begins from the perspective that for a large majority of the activities the current definition is fine. It seems to work. And that is to say that the definition for whatever the problems some people may have with it that for many it defines the activities that ought to be reviewed. So the thinking was not to throw out the current definition of research but to include it as one of the categories of activities that should be covered.

One of the things that we did that I found interesting when we reviewed a number of the ethics codes was that many disciplines use the term "research" but they do not ever define it. They seem to know what it is but it is not defined. And so again the way that this was written is you can use the current definition of research or, you know, if a discipline uses a

different definition of research, if it is research it is a covered activity.

So what we then are trying to do in the categories that go beyond the first category is to try to describe activities where it may be questionable whether they are called research or not or it would be debated. Some great minds would say it is research and some great minds would say it is not research but there are other characteristics of those activities that would require that it would fall under review of an IRB or under the federal regulations and that is what we try to accomplish in these other categories.

The other categories -- I do not want to go through all of them because I think that they can be discussed. I want to point out that it is deliberate in this that they are not mutually exclusive and while from a conceptual standpoint that may be uncomfortable or not appear clean, from a practical point of view and sort of from my own experience of knowing what researchers do or investigators do to avoid the IRB process, these other categories are written in such a way to try to capture as many of those activities because -- well, let me say no more about that but it is written to try to capture as much as opposed to not doing as such.

So I think what I would like you to do is to discuss them. If you want to know about specific activities that would seem to fit into one of the categories versus another category we can certainly have that discussion.

DR. SHAPIRO: Thank you very much. I will turn in just a moment to commissioners. I just want to underline one of the things that Marjorie said that as we go through this we should not have in our minds that all other aspects of the system will stay as they are because, for example, we might do things to expedite a lot more categories a lot quicker as a possible. I do not want to suggest that but that is a possibility.

So we have to be -- as we think about this we have to try the imaginary thing we have to think about, is this will be followed by some perhaps new and transformed set of regulations using both expedited review or any other aspect of the system you might think about.

Now I know that is not always easy to keep in mind but I just wanted to reinforce that aspect of what Marjorie said so let's just now go to questions.

I have Alta and then Bernie.

MS. CHARO: Thank you, Harold.

First, I want to thank you, Marjorie, and the

rest of the staff because this is moving us along finally to something very concrete. I also want to apologize because having seen this ahead of time I should have seen in it the comments I am about to make it now but sometimes it takes a while before it hits you.

The one I would like to start with is really a big picture question about this. This proposed -- this proposal here is written on the assumption that everything that is currently considered research should continue to be subjected to IRB review even if that means just to get an exemption, right, plus there might be additional things that we want to have given IRB review.

I would like to ask whether we do, in fact, want to only expand the category of things that should be subjected to IRB review versus removing essentially sub-one here, which says that all research is going to go to an IRB, and simply start with -- I think they call it zero-balance budgeting. Start with a zero-balance budgeting approach in which you say what are the things that we actually think should go through an IRB. I am open minded on the answer but I did want to put the question on the table.

DR. SHAPIRO: Zero-based budgeting?

MS. CHARO: Zero-based. Thank you.

DR. SHAPIRO: That is not an ethical issue.

(Laughter.)

DR. SHAPIRO: Do you have some examples you would like to give because I think it would help sort of frame in our mind just exactly what you have in mind?

MS. CHARO: Well, in fact, I think some of the things that were being discussed this morning are examples. I have colleagues at other institutions, of course, who might do a number of interviews as part of the background research for an article that is essentially an analytical piece but they want to get some empirical information to inform the analysis.

That work would be considered research with human subjects that would have to go through an IRB even though it is quite akin to journalists -- journalistic kinds of interventions. But because it is taking place in an academic setting I suspect it would be viewed as research. Certainly they are attempting to be systematic.

It is not that they had to randomize but they are trying to, let's say, interview everybody who ever worked as an undersecretary or above in a particular government, whatever.

This raises in my mind the question of whether or not we want to automatically assume that such an endeavor because it is systematic necessarily is something that we want to have sent to an IRB. It may be that we cannot do better than the current definition and we want to focus our attention on exemptions and expedited reviews, which is what we did with HBM. We swept it all in and then figured we would clear it out.

But it has a procedural significance here because if something is not -- whether or not something is considered research is a personal judgment call made by the individual who might or might not have to approach an IRB and say please review me. Right? But if we call everything research it means those individuals are under a substantial obligation to approach their IRB's and then it is either somebody at their institution or somebody affiliated with the IRB, depending on how they set the structure, who has to make the judgment call about exemptions and expedited review.

So there is a procedural significance about whether we want to force people to presume that they need to approach somebody and then get exempted out or whether we want to give them the control themselves to decide if they need to present themselves for

regulation.

DR. SHAPIRO: Steve? This is on the same issue, please.

DR. HOLTZMAN: Absolutely.

DR. SHAPIRO: Okay.

DR. HOLTZMAN: I just want to completely endorse what Alta is saying and how it brings into the frame how you have got at least three moving parts here, right. You are going to have research, however we define it, equals IRB review.

Number two, what is a human subject, right? Because you are going to have human subjects research and that is going to be gating on whether or not you are either in frame or not for IRB review and how is that determined.

Then the next cut at it is if, in frame, does the IRB make the exemption call or not? So I think it is hard -- we have to start somewhere to nail down the flaps in the tent, right. And one is to say do we mean if it is on this list it goes to the IRB?

Albeit it could go to the -- that is it is human subject's research and the IRB now makes the call whether or not it is exempt and/or subject to expedited review. That is one place to get at least one flap down.

And then we might then -- as Alta said, you may say, well, therefore, that is what we mean. We may have to look at this more tightly and I would argue ask the question is research too wide as opposed to simply too narrow.

DR. SPEERS: Could I --

DR. SHAPIRO: Yes, go ahead.

DR. SPEERS: I will tell you what my intention was and that is to say that these would be activities that would fall under the federal regulations, whatever those federal regulations are, which is not the same as saying that they would receive an IRB review, which is the way the system is now, which is that the activity falls -- becomes a "regulated activity" so it is one that has to be looked at but it could be exempt under the current system or it could be expedited or have a full board review.

DR. HOLTZMAN: So let -- something I have never been clear on. The first cut is it subject or not? And who makes that call is an important point to be addressed.

The second is it is subject but it is exempt. Who makes that call because it has been unclear to me and maybe someone has an answer to that question. Currently does the IRB have to be the one who says yes

but it is exempt and then the -- and the expedited is a different kettle of fish. You know you are in.

DR. SHAPIRO: Alta?

MS. CHARO: But this -- actually to clarify, and I will take corrections from anybody here if I get this wrong, my understanding is that although the control of the definition of the term of research lies with OPRR, in practice it is investigators themselves or it is individuals themselves who decide whether or not other are investigators engaged in research or they are individuals engaged in some other activity.

And that means that if they do not think they are doing research they simply do not present themselves to an IRB. Now if they are in an academic department maybe their chair sees what they are doing and disagrees and holds them up or something but the first cut is that they make that decision for themselves.

Once they have decided they are doing research it may be exempt but most MPA's are written in a way that does not allow an investigator to decide for himself that he is exempt. Instead the decision that something is exempt is made by a disinterested party. It might be their supervisor, their department chair, the IRB administrator, the IRB chair but it is another

person so that the distinction of whether something is going to be called research even though it is subsequently exempt versus not called research is significant in terms of whether or not there is an initial contact with a disinterested party, which is the first point of contact at which some people complain that already the burden has gotten to be too great, and that this is interfering with their lives, and that it is covering activities that should not be covered, and that is why I just wanted to put it on the table as whether or not we want it to be broadening only or potentially narrowing the scope of activities.

DR. SHAPIRO: Other comments?

Yes, Bill?

DR. OLDAKER: I think having been an old lawyer in the government and prosecuting for a long time, one of the problems with having an overly broad rule is that, in essence, what happens is that people soon start to disregard parts of it and I think that if we really have risks that we are worried about we want to make the rule as narrow as possible so that people will respect whatever that rule is and follow it.

DR. BACKLAR: Hello.

DR. SHAPIRO: That sounds like Trish, yes. That is Portland, Oregon talking.

Trish, can you hear us?

It is dead now. I am sorry, Bill.

DR. OLDAKER: No. The point merely was I think that one of the things that we heard today was that a lot of people get swept under this rule because of the various interpretations that are made and I think that that becomes problematic in and of itself. If the rule attempts to cover too much, sweep too many things in it, that the real areas where the risks occur get less rigorous examination than they otherwise would, and that is just normal. That is normal human nature.

So I would endorse what Alta is saying about zero-based budgeting or something where you basically look at the bottom line of what really should be regulated and then build up from there instead of looking at it trying to encompass everything and then narrow it down.

Thank you.

DR. SHAPIRO: Okay. Bernie?

DR. LO: I wanted to clarify for myself sort of the purpose of what we are trying to do here. In our previous discussions we had a fair amount of agreement on the thought on the need to enlarge the scope of the regulations in two ways.

One is to sort of leap over the divide between federally funded and nonfederally funded and not in an MPA and not submitted to the FDA. Activities that were clearly research in anybody's sense of the term where there were substantial risks, which could go theoretically unregulated whatsoever, and that was, you know, the unanimous thing that passed a while ago.

So that would fit under the category you were just talking about, Bill. Things where there is a perception that there is a substantial likelihood of significant risk.

The other area that we have talked about enlargening are activities which are on the gray zone between research and something else but present again significant likelihood of serious risk so this would be in the medical arena manipulations with large databases where clinical information somehow gets used for business purposes or quality improvement, or advertising, but the risks to privacy and confidentiality are the same as if you did the same thing and called it research. I think some of us were uncomfortable with the idea of saying depending on whether you classified it as research or something else, if you could get some scrutiny or substantial scrutiny or no scrutiny at all.

Then I think there is a lot of concern in the public about just needing to pay more attention to privacy and confidentiality in general. This is the whole HPPA health privacy legislation.

Certainly in some course of the sense the way you have got these things that are IRB's, we can either ask IRB's to do more of this general privacy or set up things that are like IRB's and call them privacy boards.

I am just wondering as we think about enlarging potentially the scope of some of the things we consider research how far are we going to go because on one level you could argue that anything that involves a breach, the risk of breach of confidentiality that has substantial wrongs or harms attached ought to be reviewed by someone who is not sort of just doing a project.

But I guess, you know, the other way to get to that I would sort of comment on what Bill and Alta were saying, it is not just a matter that people start to ignore or flaunt the regulations, it is that we have currently an IRB structure to which a lot of concerns have been raised over whether they have the expertise and the resources to carry out the tasks that we would all like them to do.

And one of the things we have struggled with is as we have given them more things without necessarily guaranteeing resources or taking things away, is it become unwieldy. So I guess I am a little concerned.

I mean, I -- I am not quite sure what it is we are trying to encompass. Is it that these are things that are like research in a sense there is a substantial risk of wrongs or harms and activities that are not directly to the benefit of the patient unlike clinical care?

What is sort of the general criteria that we are sort of trying to enlarge things in? And that -- if we answer that it may answer Alta's question of what should we be excluding.

DR. SHAPIRO: Jim, then Larry.

DR. CHILDRESS: A couple of points. I guess one question I have and maybe even a concern is how feasible it is actually to try to redo the Common Rule and get something through since presumably this would have to be incorporated into that and what time frame we might be talking about but also whether that really is the problem we have heard or whether the problem really is one of interpretation of the Common Rule.

And that given its traditions of practice of

interpretation by IRB's that may be creating the problem and at least I have not heard so much in our discussion at this meeting and before that the problem really is what the Common Rule says on its face rather than the way in which under various pressures IRB's are interpreting what is research and what is required in evaluating research involving human subjects. Again because of the pressures within institutions.

So I am wondering whether if we do decide to go this way, recognizing that it will be a difficult task, we probably also ought to be working on the other level, namely how to deal with and perhaps correct traditions and practices of interpretation.

And just to add another point, it seems to me following up on what Bernie suggested that if we were looking at the kind of research that was largely focused on this morning, the issues were to a great extent privacy and confidentiality issues and that is obviously sort of a background of the -- or part of the context in which we are thinking about that sort of research but we may need to address that more specifically or society is attempting to address it more specifically in other ways, and obviously this is simply a part of the whole system that connects with those larger concerns.

DR. SHAPIRO: Thank you.

Larry?

DR. MIIKE: At the risk of jumping in when I just walked in but I did communicate to Marjorie when the definitions issue came out was that it was not so much as trying to change the definition. We were trying to -- it was an attempt to enlarge the scope of what would be reviewable.

It seems to me the straightforward way -- and I have said this before, the straightforward way is what is this kernel question and we are really talking about consent, conflict, safety, privacy and confidentiality.

I remember Dr. Levin in our earlier testimony saying he would rather see the exempt and the expedited process all put together instead of haphazardly deciding what is exempt and not.

So it seems to me that where I would be heading towards is that what are we really trying to minimize in terms of issues here, harms and autonomy issues here, and from my standpoint if we did not -- and of course we still have to make a judgment about whether -- I think we will be heading more toward a local and central type of hybrid where there is strong feeling out there that it really should be a local

decision but they are dying for guidelines.

I just came back from a health services research or a health research group in HMO's and it is quite clear that the local IRB's do not have any guidance whatsoever on interpretations. Like they would ask me, we would really like to know what practical goal means, but there really is no guide out there and so there is no consistency.

But in order to get consistency even without any more formal helping hands from above by some federal agency or something where you suggest that it is created, a body that keeps on looking at these issues starts to develop its own consistency.

And so it seems to me that aside from the issue about whether there is authority for such a thing as IRB's or even us to suggest that there should be oversight over something more than research, it just seems to make imminent common sense that within an organization that takes those oversight responsibilities, they are looking at the problems they are trying to minimize at and regardless of whether it falls under the Common Rule or some other aspect that they will go ahead and do it.

I think you can do that and -- for example, one of the -- then you would have to see what the

process is and, for example, right now I think that the -- what is allowed under expedited review is too narrow.

I would actually say if one meets the standards of minimal risk and one would have to address the issue about privacy and confidentiality in terms of what minimal risk is that there be an assumption that that is an expedited review rather than this other issue about it has to be minimal risk and here is these limited categories under which expedited review can go forth.

So I think that on one hand you increase the responsibilities of bodies such as IRB but you also make the task a little bit more flexible and easier and then obviously everybody is crying out for more guidance and I think what they mean is that instead of OPRR just coming through and reviewing our paper and seeing whether we followed the regs, they sure would like somebody up there that can give them more guidance in terms of what these kinds of -- what these regulations mean in particular instances and in definitional issues.

DR. SHAPIRO: Diane?

DR. SCOTT-JONES: I want to agree with what Jim said just a little while ago about what we have

heard today so far and the issue of defining different kinds of research and not so much as defining issues as research and not research. I think we need to give more thought to that to making sure that all of the various kinds of research are reviewed in a way that is appropriate.

DR. SHAPIRO: Alta?

MS. CHARO: Two points. First, I share Jim Childress' concern about how realistic it is to do anything that deviates from the Common Rule. On the other hand, since according to Marjorie's initial memo we are also considering implementation of our resolution about expansion to the private sector we are necessarily in an arena in which federal action -- congressional action is needed so that in a sense the door has to be propped open for that so we can let, you know -- we can let the rest of the herd walk through with the first animal.

On the question about the scope of coverage, right, when I ask myself why I want third party review, IRB review, the answer usually comes back that I want review in those circumstances where people will feel used against their will or just feel exploited. And within that group of people there will be some who are perfectly capable of protecting themselves so it will

be a subset then that I think really need the IRB review.

So it is wanting to prevent people from feeling used in situations in which they are not fully capable of having protected themselves and that is why you would suddenly invoke all of the machinery of the Federal Government.

Do we, I ask myself, really want oral history projects as a rule to be subject to federal regulation since it is a circumstance in which people generally do not feel used and abused and incapable of having sensed that problem early enough to be able to protect themselves.

Or when somebody does a survey of alumni asking their attitudes about the curriculum and what people should -- what skills they should have when they graduate and, you know, do we really want that to be subject to federal regulation or do we want that to be able to proceed a pace.

If that is the case for me then I would probably want a somewhat narrower scope of things that even have to get an initial look see by an IRB official or by some higher up because I want to avoid having a tremendous amount of stuff heading toward the IRB's even if it is for an initial clear out through an

exemption procedure.

You could accomplish that either by writing a narrow definition or by writing a wide definition with a then series of special exceptions that say not withstanding the above the following activities are not going to be reviewed by IRB's: (A) Journalistic interviews. Right? (B) Student evaluations of teachers. You know, whatever your list is going to be of things that actually technically would come under the language.

But my inclination is to kind of narrow it a little bit up front in part because I think actually that Bill Oldaker's comment is well taken that to maintain respect for the system we want to have people see a connection between the activities that are being overseen and some sense that there might even be a problem that needs to be overseen.

DR. SHAPIRO: I also have a little different perspective, I think, Alta, and maybe -- I am not sure that I have got it right either.

If you take this morning's testimony, which was only one aspect of a lot of things we have heard, I do not want us to be too focused on what we heard this morning because we have heard a lot of testimony. I was not at all reassured by what I heard.

Mostly what I heard is either things had not been done and, by the way, do not bother me because we have important things to do in life and we are a little bit annoyed that, you know, someone else might take an interest in the protection of human subjects.

And so I have a rather different view. I think that having a -- we need a system that works obviously. A system that is over burdened, that has unnecessary bureaucracy is all a bad thing, and we have to address that problem, and I completely agree with what Bill said in that regard.

But it seems to me just by way of proceeding as we go down this road, as Steve said, to start putting some flaps down and then we are going to have to come -- we are going to have to circle back and adjust but we cannot come to any conclusions today. It is really rather dangerous to get narrow up front.

DR. BACKLAR: I have my hand up.

DR. SHAPIRO: I will turn to you in a second, Trish. Thank you for telling me.

And, therefore, I think it is actually a better strategy to draw the circle not excessively widely but to take a broad set of activities and then ask ourselves what is a useful -- these are areas where there are human subjects. It is human subjects

protection that we are really focused on. It is not the efficiency of historians that we are focused on or the efficiency of molecular biologists or psychologists or economists. That is not what we are focused on.

What we are focused on in my view at least is human subjects protection but we have to find a way to do it in a way that is not, you know, unnecessarily burdensome and stunts all kinds of important activities and so on.

So it seems to me as a strategy that we ought to proceed in a way that says, you know, one of our roles is to look out for vulnerable subjects out there. There is all kinds of powerful interests on the other side who will weigh in over time and, therefore, we ought to draw -- for purposes of the way we go about it, draw it rather widely and then, as you pointed out, I mean you have pointed this as a second strategy yourself, say, look, how can we make this as simple as possible. And so -- and that goes to whether it is exemption or expedited review or something.

I actually think it is rather healthy for people conducting, just to use two examples you gave, alumni surveys or surveys of students to have to stop and think about what this means not for themselves in their own needs but for those people that they are --

who are answering these questions and it may be just a four minute thinking that has to go on there but it is rather healthy to do that thinking, I think.

And so I really favor keeping it broad for the moment understanding that we may circle back after we develop machinery in here and draw some things out. I think that is entirely possible and I certainly want to allow that.

But let me turn to Trish.

DR. BACKLAR: I have been listening all morning and I actually really was extremely pleased at the end of the morning, Harold, to hear you voice some concern about the risks that still may be there for subjects and I was also very pleased just now to hear Alta say that people should not be used against their will. It is the subjects who really need to be protected still and despite everybody's -- many people's talk this morning about consent, that they were being overly reviewed and had too many impediments put in their path, so I am -- all I am really doing is saying that I agree with you, Harold.

I think it is terribly important that we do not forget why we are doing this. I did want to say one other thing, though, that was -- when Steve spoke about the issues about privacy I just thought that the

term now -- the title of that paper by Mark Seager should probably be privacy is a decrepit concept, and I do think that that is going to be of great difficulty for us.

DR. SHAPIRO: Thank you, Trish.

Trish, just yell out whenever you want to speak since it is hard to see your hand from this distance.

DR. BACKLAR: I know. I regret having to interrupt you.

DR. SHAPIRO: Thank you.

Bernie?

DR. LO: I want to follow up on this idea of trying to include what ought to be included but not sweep so much in that it gets unwieldy.

Harold, to pick up on your point, I think it is healthy for whoever is doing a project, whether they call it research or not, to stop and think about the impact on the participants and the potential risks and are they vulnerable.

But I think that if we can identify for various big broad categories of research the kinds of protections in the conduct of the study and the selection of subjects that would move it into a minimal risk category to use Larry's term. I mean, if I am

going to do a survey, yes, I should think about what the impact is on the people filling out the questionnaires but there also, it seems to me, should be a way of defining criteria by which I could then say if I do all these things it is going to be close enough to minimal risk or minimal risk that I do not have to go through a very elaborate IRB procedure.

And I think the real concern is not so much that people do not want any oversight of what they are doing but it is the concern that if you allow any oversight it is going to be so unwieldy and require so much sort of back and forth and paperwork that it is just not worth either doing the project or it is not going to save -- it is not going to prevent a lot of wrongs or harms.

So I think one way to try and get out of this is to define within broad categories of activities the source of things that would qualify for either exemption or expedited review, which would require very little interaction provided you conducted the study in certain ways.

DR. SHAPIRO: I mean, I think we all agree with that and I certainly agree with what you have to say.

Arturo?

DR. BRITO: Alta, when you were making your comments initially I was following along and said, yes, I endorse this and I agree this wholeheartedly but there was a point there where I became a little bit anxious and my anxiety, I think, is because, of course, we need to make things more clear and I have a question for Bill actually about that but we need to make it more clear and probably more narrow.

Where my anxiety comes from is if we make things so narrow that there -- those that are not so concerned about the subjects, and there are many people that are not concerned about the subjects that are involved in research or not as concerned as certainly people that are involved in ethics on a full-time basis or what have you, and what we heard this morning institutions themselves are often motivated by amounts of research.

Would they be able to find more loopholes? You know, I am just thinking this out loud when you were saying that. Would they be able to -- something about what you said made me feel like there will be more loopholes by making it so narrow that, you know, you would say, okay, these things -- this list of things is exempt from IRB review. It does not need to go to IRB but by extending that list of things that

would be exempt would there be more loopholes?

So my question to Bill related to this are we really talking about making things more narrow when we say that -- so it becomes more -- or are we talking about things -- making things more clear or are they one and the same?

DR. OLDAKER: My feeling is you have to make things more clear. Clearness by its very nature makes things more narrow but if we look at the risks, I think Bernie said, if we look at biomedical research, I think, and human subjects, clearly it is covered. I mean -- but when you get to the outer fringes I think, number one, the risk factors are high there and so I think, you know, if we look at it from that standpoint we say we definitely want to cover there. I think in psychological studies and other things the risk factors are also high there to the subject.

I think you have to look at it from the risk factor to the subject and also, as I think Alta said, I think you have to look to the vulnerability of the subjects but those are the two concerns and they have to be balanced.

You could do it -- either way you could build up or you could build down. Either way that you do it you want to have a rationale for why you cover what you

do cover. I think the risk of covering too much is that when around the edges people start to believe that the rule is ineffective or it is covering things that should not be covered then that kind of permeates the whole system.

If we are dealing with the -- basically the federal system now that is one thing. When we try to go to the private sector the ability of enforcement gets much greater. You have to have a much greater feeling about the people who are going to be regulated that there is a reason to be regulated. So I think, you know, we have to pick out -- I do not care whether you do it from up or down but you have to basically say what are the risk factors, what are the bright lines that you can draw.

Now you may decide to make some things broader just for safety sake but I think I would -- I think definition is what you are talking about. I think that is really what you are trying to do is make it as clear as possible and there is always a risk in regulation that it is easier to draw the very, very broad fence but I think that that -- in doing that you do not accomplish what you want to do. You accomplish actually the opposite.

DR. SHAPIRO: Thank you.

Tom?

DR. MURRAY: I found myself in great sympathy with Harold's wanting to begin with the big picture and then I started having all these troubling thoughts. Suppose the admission's department at Princeton wanted to do a marketing survey just to see how effective -- whether their materials were being read and, you know, what the return rate was. Is that human subjects research and ought that to be reviewed by an IRB?

It seems to me -- and then I went back and I said, well, where would that be covered and I read number three and I will just -- for those of you who do not have a copy of this, I will just read it quickly. Activities undertaken with individuals that have multiple purposes where at least one of the purposes does not involve direct benefit to the individuals and is undertaken to provide information to the persons conducting the activity, their organization or another entity.

Well, that seems to be pretty clearly cut but so would market surveys by private companies also be covered. We have got to have some other limiting conditions or principles there and at this point I just want some help. It could be from anybody. Marjorie, Harold or anyone else.

DR. SHAPIRO: There is a lot of people that want to speak and I have got a good list here and I will turn to them in a second. I think that there is actually more agreement amongst us than disagreement here. The question is not whether we are going to have to find some things that limit the scope of what goes to an IRB, which is already up the stream a little bit.

We clearly want a lot of things that are encompassed here not to go to IRB ever and the question is when do we start focusing on that issue? Do we try to -- as I guess Steve or someone said or Alta -- have the issue rather broadly defined, see what mechanisms we try to put in place, and then start carving issues out or go the other way around.

It could work either way. I mean, it is not a logical --

DR. MIIKE: Can I just answer Tom?

DR. SHAPIRO: Yes.

DR. MIIKE: I think in the current system there is a two pronged approach. That is just one of the areas that is mentioned but I would argue that the current definition of research would exclude those marketing studies so that there is -- it is not that just because it fit that situation --

DR. MURRAY: But that is what I am --

DR. MIIKE: Yes, but what I am saying is if we are going to design a new system my -- under the current system that would not be included but if there were some risks involved then those are the kinds of studies we would like to be included. I think what we are starting -- what we are going to end up with is a system like Harold says which is broad and then we are going to decide not only which ones we want to exclude but who has jurisdiction over what. I mean part of the issue here is that -- is it the Common Rule that it is going to apply or is there some state or institutional privacy policy or federal privacy law that will apply.

And then the question is, as again I said, I would rather have one body dealing with all of those because you have a consistency in, you know, those kinds of issues.

DR. MURRAY: Just a quick distinction. One, I am not sure it is going to be helpful in the end but one of the earlier speakers made the distinction between the use of say scientific methodology to answer questions for whatever purposes. So a well designed marketing study that does a good sample.

Versus science, which is an effort to generalize something like -- an effort to create

something like generalizable knowledge. We did include -- that was included in the original definition. I am not sure whether we want to retain that kind of distinction or not.

DR. MIIKE: But all I am saying here is that we -- I remember a speaker saying, well, you know, we do these things and it is designed -- we do these other things it is for generalizable knowledge and my answer was, yes, but you are just parsing it out. It is the totality of it all that applies, not just the little phrases that make up the whole statement.

DR. SHAPIRO: Steve?

DR. HOLTZMAN: Part of me says, Harold, that we are all in agreement and part of me thinks that there is a very important first step here which we better not slide over and I think Alta was pointing towards it.

It can seem that pragmatically whether you say something falls within the scope or it is exempt does not matter and maybe you could pragmatically make it straightforward about how to get an exemption and it would not be a problem.

But Alta raised the question what is the proper scope of government oversight even where that oversight may be nothing more to say than this activity

is exempt. So take your example of that marketing study and I found myself saying, you know, I can sit here and think about my interests and opening my mouth and making these noises. It would be good of me to take into consideration the impact on all of you. Clearly I do not do that, right.

(Laughter.)

DR. SHAPIRO: We will answer that later, Steve.

DR. HOLTZMAN: Okay.

But the truth of that statement does not mean that this set of social interactions in which I am engaging should be one which is the subject of government overview albeit an exemption. So I think there is an important first step there that we cannot just obliterate.

DR. SHAPIRO: I agree. I agree with that.

Let's see who I have here. Marjorie and Eric wanted to say smoothing.

Marjorie?

And then Diane.

DR. SPEERS: I wanted to just address the question a bit that I have heard here of what are we doing a bit and try to give you some thoughts on that.

One of the things that we are trying to do here is to reduce some of the ambiguity that exists now.

For example, I wrote down three examples. One is program evaluation. Is program evaluation research or is it not research? Surveillance, is it research or is it not research? Quality improvement, is it research or is it not research?

You have heard about all three of those activities and, you know, if it is called research it falls under the regulations and if it is not called research then it does not. And so we have a system now that has a double standard in it. It does not even matter about the funding. It simply matters of how you call it, whether you call it research or nonresearch.

And so one of the things I think that we are trying to do now is to take out some of that double standard and to take out the simply if it is research -- if it is called research or not called research, you know, having that be the cut that is made.

The other point that I wanted to bring up is that in all of these categories -- or I take that back. In the first -- in the categories up to number six it is assumed if it is not explicitly said that there would be risks. And this notion that, you know, are we

trying to include activities here that do not involve risk, no. In those first six categories it is assumed that they all involve some risk.

And so perhaps the question for you to consider is when we talk about risk are we really only talking about significant risk or are we talking about any kind of risk, any level of risk? And what is the importance or significance of the dignitary risk or harm? Because again for many of these types of studies that are on the fringe or on the margin the risks are either a dignitary risk or harm, informed consent, or it is the privacy and confidentiality issues.

Those are the ones so, you know, just to drive the point home if we are talking about a medical records review or we are talking about student records or -- let me just start with those two examples.

The primary concern with either one of those could simply be the issue of consent and the dignitary risk. So to me it depends in part of how you want to think about risk as to then which of these categories may remain or not remain in this.

DR. SHAPIRO: Thank you.

Eric?

DR. MESLIN: I also wanted to put some context into this. You have heard testimony at several

meetings now, the purpose of which was to present you with examples of activities, be they research activities or other activities, that are either not currently perceived or widely understood to be captured under federal regulations. And if you do not believe that was the case then you can simply look back to all the discussions that the National Commission had and the President's Commission had and see how often oral historians were presenting before the National Commission and the President's Commission. The answer is none. No times.

So the question that came up earlier as to whether a taxonomy or a case based approach can be developed is what we have been doing the last couple of meetings and I would in a sense encourage you or remind you to not go to the alumni marketing example but to the six presenters we have had so far and the six we had at the last meeting and make an assessment on your own as to whether the cases that they presented and were living embodiments of were just as a heuristic activity in or out of this model. Yes or no? And you do not have to answer but that is -- you do not have to go outside with all due respect to Princeton's Marketing Department.

Go to the oral history. You know, go to the

anthropologists with the Ogdala Sioux and come to your own initial assessment.

I say that because following Steve and Bill's points I think the challenge we are trying to present you with or force you to make a decision about is whether the are activities that are not already covered or well covered, and I use the word covered on purpose as opposed to regulatorily defined IRB review or not, but generally covered as a matter of principle or ought to be covered.

You did this in the capacity report. You looked at the federal regulations and you made a decision that there is a population out there that are not appropriately or sufficiently well covered in regulation and you made 21 recommendations to change federal regulations in that regard.

On the other hand, you have a choice to look at those things that are already covered and decide whether what is missing following on Bill's suggestion is more clarity, more care, more attention. You did that in the HBM report. You said the regs are pretty good but what is needed is a set of more clearly defined guidance that you have actually told OPRR they ought to interpret the guidelines in this way.

And I do not see those as mutually exclusive.

You have been given, you know, thanks to Marjorie's excellent work, you have been given as many cases without going outside this room as you probably need and we can find lots more. We have not brought the political scientists here. We have not brought any of the other organizations that Carrie Jo was able to track down in two pages of notes for you.

The only other thing I would say is in following up on Tom Murray's earlier question about Don Chalmers' paper, among the reasons that we want Professor Chalmers to present a paper for you is because Australia is one of only two countries, Canada being the other, that decided within the last two years to broaden their national guidelines to cover all of the things that you have heard.

You may want to ask Professor Chalmers and even Bernard Dickens when he comes to the Madison meeting next month because he is expert in the Canadian system as to whether that broadening, although it is too early to tell, has had a good effect, has had a bad effect, has had no effect, and if you would like staff can contact directly those oversight bodies in Australia and Canada and ask them for the early returns. Are the IRB's up in arms in those countries? Are the investigators saying thank goodness for these

guidelines?

So I am just reminding -- basically building on what Marjorie said and reminding you how you already have some of the tools to think through some of this.

DR. SHAPIRO: Diane?

DR. SCOTT-JONES: My question has changed a lot from the time that I raised my hand just listening to Marjorie and Eric and Tom and other people so let me sort of try to say what I am thinking right now and I am not quite clear on the purpose now of the draft recommendation because if I understood Marjorie and the original purpose that I understood before coming to this meeting, this recommendation is to -- was to enlarge the definition of research to include activities that are not often considered research such as surveillance.

But, Eric, if I understood you just now, you are referring to the social sciences and I would like to register just a gentle objection to my discipline being research with quotation marks around it because I think it is research without those quotation marks and I would like just to have more clarity on whether we are considering the social sciences and how they are related to biomedical research or are we considering other activities that would not even be actually in the

social sciences, in psychology or anthropology or other of the social sciences.

I am not clear now on what we are doing and I would really like to get some clarity on whether we are talking about the relation of the social sciences to other sciences or these other activities that many people have not even considered research at all.

DR. SPEERS: Let me try to clarify. This recommendation is not about the social sciences versus the biomedical sciences. What this recommendation is basically trying to address is that within any of the disciplines, any of the disciplines that, if I could say conduct -- any of the scientific disciplines, although I do not know what I just did to humanities there but within any of the disciplines that conduct research that is covered.

Whether they use the current definition that is in the regulations or if they have another definition, if it is research and they call it research it is covered under here.

DR. SCOTT-JONES: Right.

DR. SPEERS: What we are trying to do in these additional categories is to capture those activities where it is questionable for whatever reason, whether it is research or it is nonresearch, but what is at

stake is that there are risks involved in those activities to the individuals who participate in those activities and, as these categories, say there is no direct benefit and we did not say direct medical benefit because we were thinking more broadly than biomedical research where there is no direct benefit to the individuals who participate in those activities.

DR. SCOTT-JONES: And then just as a follow-up comment then there is another big issue and that is the issue of the social sciences and the biomedical sciences in all the various points that we heard from our last panel. So there is another big set of issue that we need to consider, right?

DR. SPEERS: That is correct, which would not fall -- which I do not think falls under this recommendation but it falls under other recommendations that I hope that we will consider that would deal with the nature of the review, the type of review and what might be required in a review for those different types of sciences.

DR. SCOTT-JONES: Okay. As long as we are not considering psychology on the fringes I am okay.

(Laughter.)

DR. SPEERS: Right.

DR. SHAPIRO: Well, we could have a little

poll and to take other recommendations such as that but in any case I have five people on my list now and then we are going to take a break. It does not mean the discussion will end. We will take a break.

DR. BACKLAR: I have a question, too.

DR. SHAPIRO: Okay. Trish, you are on the list. You will be number six on my list here.

I have Bernie, David, Alta, Larry and Trish and I know I had one other.

DR. DUMAS: What about me?

DR. SHAPIRO: Rhetaugh. Rhetaugh Dumas, right, you are on here. I could not read this. I have "R" but I did not know what the initial I had after that. I apologize for that but Bernie.

DR. LO: I want to follow-up on Eric's suggestion that we try and think about specific cases or situations and I would urge that we think of two categories and then try and fit in cases in each and see if we can agree.

The first category are things that now are typically not coming before IRB's that we think ought to and I think, you know, Marjorie, you summarized what a lot of people suggested. Things like quality assurance, program evaluation particularly in small programs of vulnerable populations have many of the

characteristics that would want us to put it in that category.

It seems to me keeping with the spirit of sort of zero-based budgeting we also ought to keep a list of things that we want to sort of take out of the IRB process or at least put it in an expedited exempt category and I think there is a lot of survey research that does not deal with sensitive topics, does not deal particularly with vulnerable populations that I am not sure needs to go before a review body provided it has certain protections built in the protocol for safeguarding the identity of the individuals.

So I think if we can agree on some things that ought to come out and some things that can come in we may be able to work back from the general cases and see what broader categories are they exemplars of. It is a little hard with the general definition to see what we exactly mean by that and we may be able to agree more on the specific cases.

DR. SHAPIRO: David?

DR. COX: So Bernie basically dealt with my thing. Fundamentally I am concerned in this whole process as I talked about earlier today that people just do not take this serious. So no matter what we do it will not make any difference unless we get them to

take it seriously.

Well, one of the ways to get people to take it seriously is to take the things that they think are trivial and not have them included but at the same time then take the things that are not in there and put them in. Just what Bernie just said.

So I am very keen on that approach because ultimately we have to do something to have people consider this a serious topic and I think that not enough people do.

DR. SHAPIRO: Alta?

MS. CHARO: I am still back on your comment awhile ago, Harold, about the lessons to be learned from the testimony that we heard.

I also heard a great deal of resentment of the rules and a lot of descriptions about ways that people would like to get out of them or around them.

DR. SHAPIRO: I agree.

MS. CHARO: Fair enough. I may be more sympathetic to their frustration because of my personal familiarity with people who have gone through -- we have got multiple IRB's at our institution and there are IRB's that deal with the social sciences particularly and there are stories people have about going through that IRB are hair raising.

I think I draw a slightly different lesson, therefore, from what I heard. In these fields and in some of the others where we have heard testimony in terms of program evaluation and outcomes research and such, I find myself thinking that the frequency with which there is going to be any person who feels used and abused or is actually harmed seems like it will be pretty low.

And where the frequency of some kind of harm is low I have to ask myself if there are alternatives to federal regulation. In some cases there are. For example, professional codes of ethics can operate to constrain the people within those disciplines completely independently of federal regulation.

Second, there are post hoc solutions that provide remedies for people who have been injured and are supposed to, therefore, create a deterrent effect in the future so that some things would be recognized under the tort system as invasions of privacy, defamation, that would give rise to a cause of action that would send a message to a field that this goes beyond the pale and equivalent to medical malpractice.

So that just as in the field of medical care we recognize a range of disciplinary phenomenon I would want to make sure that we keep in mind that that range

exists here as well and ask in these areas is the remedy that we want federal regulation or is it possible to say that other less global or less systematic disciplinary measures might be sufficient?

DR. SHAPIRO: I think -- I really think that is -- and I am very sympathetic to that point. I do not think that oversight equals federal regulation or that federal regulation means IRB review. These are all different matters and that is where the -- I think the creativity of our process will come in because I am as anxious as anyone to get rid of the set of unnecessary bothersome -- the thing that really are of no benefit to anybody. We ought to get rid of it. I completely agree.

I think we are all sympathetic with that. I think it is very important in our conversations not always to mistake what the umbrella is -- that is our overall area of concern versus who is subject -- who gets to an IRB, what is subject to federal regulation or tort or professional guidance or whatever.

I mean there is all -- I completely agree with you on that issue and I think as Bernie and David have also said as others, you know, it would be in error if we came out of this thinking that everything we do now is good and now we will do some more things because

there is a lot of things we do now that are not working so well and maybe getting them out of the system is a good idea so I am sympathetic to that aspect of it.

I know Marjorie wants to say something but I have Larry and Rhetaugh and Trish and then Marjorie.

Larry?

DR. MIIKE: I would like to preface my comments by saying first that my understanding -- as again I had e-mailed to Marjorie -- is that what she had sent out is really not a definition of research.

DR. SHAPIRO: No.

DR. MIIKE: But sort of the activities that we might want to cover.

I think what we will end up with is a clearer definition of research and what kinds of things it is going to apply to. And then in asking for voluntary or incentive means to cover other kinds of things that are not research.

The reason I say that is we are bound to be criticized as a commission on human subjects protection in research for expanding our charge outside the research area. That is one.

Number two is that if we want to expand the purview of established institutions both by regulation and by custom now beyond the research area that is

going to take really a lot of effort and probably fundamental changes in the acts because as we were told before we are going to have enough trouble changing the Common Rule. I mean, I do not see what is going on there.

So it seems to me that a more pragmatic way of dealing with this issue is to say -- is to provide clarity and support for organizations within institutions that do these kinds of review and encourage those institutions to adopt similar but more flexible review mechanisms for activities that raise the same kinds of autonomy and hazard issues but which may not technically fall under it because, you know, we already have models for that in terms of voluntarily covering nonfederally funded research by the pharmaceutical industry doing the same kinds of reviews when they do not necessarily have to.

DR. SHAPIRO: No, I mean that is -- I agree that that is an interesting -- well, in fact, that is a scenario we considered and then rejected in the case we have already come -- we were dealing with the cloning issue you recall that there was some thought on the commission that we would ask for certain things and other things be voluntary or encouraged and then we would see later whether they required legislation.

We rejected that in the end in that case but it might be very appropriate in this case to rely on things other than federal regulation. Okay.

Let's see. Rhetaugh?

DR. DUMAS: I would like to ask the question that has just been referred to. Do we want to expand our charge to include considerations outside of what is currently defined as research or do we want to clarify our definition of research to encompass activities of -- such as those we heard this morning that should be defined as part of -- should be defined as research? That is one question that I have.

It is not clear to me whether we have decided that we need to be concerned about working activities that currently do not fit under the rubric of research and we need to move out to include those in our considerations.

The second thing is that the reports that I heard this morning did not sound to me like activities that would not be defined as research although they might feel that there may -- must be some kind of exclusion.

So my tendency -- my inclination is not to gather additional activities that should be attended -- that are outside of the rubric of research but rather

get clear about what we are calling research and stick to that.

DR. SHAPIRO: Thank you.

Trish in Portland, Oregon.

DR. BACKLAR: It seems to me that I have some memo here that talks about a draft recommendation but I cannot find that anywhere in my material or in my e-mail. Is this something you have in front of you?

DR. SHAPIRO: Both are true. It was e-mailed and it is in front of us but mostly because we brought it, I guess. It was not handed out today I do not believe.

DR. BACKLAR: It was not a handout. In other words --

DR. CHILDRESS: It was handed out today.

DR. SHAPIRO: It was handed out today as well. Excuse me.

DR. BACKLAR: Am I understanding that the draft recommendation is these one -- these four points that Marjorie gave us?

DR. MESLIN: Trish, they were in the e-mail of a week ago as one of the many attachments that we sent to all commissioners.

DR. BACKLAR: Yes.

DR. MESLIN: If you would like, we could have

someone fax it to you.

DR. BACKLAR: Well, I am not in my office.

DR. MESLIN: Okay.

DR. BACKLAR: I am at home. Fax it anyway but I think that the first recommendation was the issue of whether an activity is research or nonresearch -- is that correct?

DR. MESLIN: Yes.

DR. BACKLAR: Yes?

DR. SHAPIRO: No.

DR. BACKLAR: Then I do not have this.

DR. BRITO: Trish, what I had e-mailed to me, and I think this is probably the same problem, I did not get the attachment. I got the first two pages and then the comments from Alex Capron.

DR. BACKLAR: That is what I got.

DR. BRITO: Right. What we have here, the recommendations, there is a list of eight that --

DR. BACKLAR: I do not have anything like that.

DR. BRITO: I did not have it until this morning. That was in the -- so I think a lot of us are like that. So I do not think you have that draft.

DR. BACKLAR: Okay. Because I thought perhaps you were all talking about smoothing that I am not

looking at.

DR. BRITO: Right. The letter you are talking about has the generalities. This is more specific.

DR. BACKLAR: Yes.

DR. BRITO: Right.

DR. BACKLAR: Okay. So in other words you do or you do not have this?

DR. SHAPIRO: We do have it.

DR. BACKLAR: Okay. So if somebody -- it would be nice if somebody faxed it because I will go and get it later.

DR. SHAPIRO: Thank you very much.

DR. BACKLAR: Thank you.

DR. SHAPIRO: Thank you, Trish.

Marjorie?

DR. SPEERS: I wanted to expand just to clarify for you a bit about exemptions now because in this discussion about scope and what would come under the regulations it is -- to me it is intimately tied with review and -- because I think about the comments that -- two of the comments that we heard this morning, which was activity should be reviewed and then the question becomes what is the review and so I wanted to elaborate on exemptions for you.

When something is now exempt under the

regulations, what that means is it is completely exempt. It does not mean it is exempt from IRB review. It is exempt from all of the requirements in the regulation so, you know, the obvious question that you will get from a researcher will be, well, then I do not have to get informed consent because it is exempt from all of the regulations.

Further, an institution, for example, is not required to have an IRB. It is not required to have an assurance. In other words, the research does not have to be conducted ethically if you will because it is completely exempt then from the federal regulations.

So at this point for some of these activities you can either at this point define them as not research so they do not fall under the regulations or they can be research and then they are exempt and they fall outside of the regulations.

The alternative, and this is particularly true for some of the activities that we are talking about that are on the fringe, and for those that are considered minimal risk activities maybe where the main risk is either the dignitary harm or a privacy confidentiality issue.

The alternative is to now put it through either the expedited or the full board review process

reviewing it according to all of the regulations that, you know, we use as we would do a clinical trial. It is the -- the criticism from the field is it is, you know, a one size, you know, fits all.

So that the issue of review, I think, is tied in with this issue of scope.

MS. CHARO: Marjorie, could you clarify what your impression is of who has to decide whether something is exempt?

DR. SPEERS: My sense of who makes that decision now or what is -- what we strive for is that it is some type of a third party. So it can be an IRB. It can be a person who has some kind of responsibility for human subjects protection. In some cases it may be even -- it may be a department chair but it is not generally the researcher.

MS. CHARO: Right. So it is not true that calling something -- it is not true that saying that something is not going to be within the scope of our regulations is equivalent to calling it exempt because the difference is whether or not the individual has to go to a disinterested party. That is the real difference there.

DR. SHAPIRO: That is right.

MS. CHARO: Okay.

DR. SPEERS: Right.

MS. CHARO: By the way -- I am sorry, Harold, but the expedited --

DR. SHAPIRO: Go ahead.

MS. CHARO:: -- review which keeps coming up, just as a matter of personal experience it does not expedite things a whole lot. It has got a great name but it is a bit illusory.

DR. SHAPIRO: Thank you.

I think it is a good moment for us to take a break now so why don't we -- it is -- why don't we try to reassemble at quarter to 4:00? It is about ten minutes from now.

Thank you.

(Whereupon, a break was taken from 3:40 p.m. until 4:21 p.m.)

DR. SHAPIRO: Colleagues, we are running quite a bit behind time and we obviously will not be able to adjourn on time. I think this may be the first of the meetings that I have chaired that has not finished either on time or ahead of time and I apologize for that but we will try to finish as close on time as we can.

Let me -- I want to turn to the material that Kathi wants to deal with but let me say a few words

about our previous discussion and we will, of course, have to come back to you on that and it has been very helpful, the comments that were made today, and we will have to sort of reassemble our thinking and share it with each other and see where we go from there.

I do want to say one or two things about that. As I think myself of the definition of research, which we can almost all repeat by heart, which is listed under item one there since we have come to it so many different times during our discussion, it is interesting to me that most of the comments we have had over the time we have been a commission and working together have to do with concerns regarding things that were not covered, things that somehow were not thought about very much as focused in the biomedical model and so on and so forth, and this was done 25 years ago and now things have changed and so on and so forth.

As I look at that definition and ask myself what is wrong with it -- I mean, it is sort of a big enough definition of research you would think it would capture the whole world and there would not be an activity that would not fall into it.

I think a characteristic of that definition is the word in the second line of it which says design. Design goes to intent and that leaves a lot of room for

interpretation. I mean, there you just do not know what is in and what is out. I mean, it is sort of you cannot sort of just tell by looking at something whether -- what the intent was.

And we -- even if we were to keep that particular definition and want to keep it at that level we would have to at least clarify that issue so we would know whether health services research, for example, one of the things that came up today, was in or out and I think as this research -- as this definition is written you could think of the exact same research project carried out by the Health Services Administration, which would certainly fall into the -- into this as a research project that they sponsored, and you would have the exact same study done by let's say an HMO for quality assurance purposes that would not come in at all and it would have nothing to do with whether there was risks or anything else involved with it.

It seems to me that that is at least one issue that needs to be clarified. I do not want to say expanded because that seems to bring other images into play here. So I think we are going to have to do something here to clarify it -- let me use that word -- so that it is more obvious to people what is in and

out, I think, and we have not done that adequately yet and we have to -- have some work to do on that.

Secondly, I think that I picked up from really most of the comments, and something which I certainly agree with, that, as Bill said first, you want this to be a workable system so people will respect it, use it and it will be effective.

I think it is a very important task that whatever we come out with at the end has to fulfill that or else it is not going to, you know -- we will be fooling ourselves regarding how effective we are.

And that means one way or another that one of the things that we have to do now, we probably want to stop some of them, and yet there may be other things that need to be done. There is going to be some churning in here as we go through this.

And we have to be especially sensitive and perhaps creative regarding if something is in that category what is the review process. Is it expedited? What does expedited mean? Is it exempt? What does exempt mean? And so on and so forth because I think we are just going to have to pay some attention to that because that is the other thing we have heard a lot of over the years, that is it is a bureaucracy with no -- with no aim somehow for many researchers.

Part of that is simply everybody feels annoyed when they have to do something they would rather not do but part of it is genuine and we will have to work our way through that so there is a lot to be done here and what I really want to ask you is that given our schedule of activities and so on we will come pretty shortly with some suggested changes in this but we need to hear from you, e-mail or otherwise, on a pretty regular basis now. That is we cannot wait between meetings to see where we all stand. Otherwise we are going to not get far enough progress.

So that we will take everybody's comments into consideration, return to this issue and see if we cannot focus in a somewhat better and more effective way, and then we will still argue a lot I am sure but at least we may start moving down towards clarifying the issues in a way that we think is moving us forward.

So we will be back to you very shortly on this issue. In fact, if we can squeeze any more time out tomorrow we might indeed discuss it some tomorrow if we can manage to fit it in because it is such an important issue. So we will get back to that pretty regularly from here on forward.

But let's now turn to Kathi to at least give

us an update, which is how I think I would characterize, Kathi, what you intend to do, regarding the summary of the results from our survey of federal agencies, which you will all recall, and Kathi has been working on it.

Kathi?

PRELIMINARY RESULTS FROM SURVEY OF FEDERAL AGENCIES

DR. HANNA: Does everybody have a copy of the survey? It should have been in your package that was in the folders, I believe, that were at the table. Because I want to just kind to walk through the preliminary data and I have to tell you that 16 agencies have responded so far. In some cases there are subsets of those agencies. For example, the Department of Health and Human Services has 11 separate responses in there for each component. So I have two stacks of paper that are this tall and have really only begun to scratch the surface.

The first thing I wanted to say is that I Think that the agencies really put in a tremendous amount of effort in completing these surveys in a very responsible way. There is a huge amount of data in there and I think that your oversight project is going to be able to mine those survey returns for the entire

duration of your project just because of the diversity of the information in there, the depth of it, and it is an enormous amount of information that I do not think you are going to be able to characterize very easily.

What I want to do is just talk a little bit about some of the more descriptive data that we have been able to quantify and if you -- I apologize for these overheads because when you are dealing with 16 agencies and about 35 subcomponents data gets pretty dense.

These are the agencies that responded and you also have that on your handout. You can see that for some of these agencies they submitted more than one response depending on the component. They had to do this perhaps because of administrative, statutory or budgetary reasons. Their budget is separated in a certain way.

And the first overhead, Stu, just gives you a sense of the budget.

(Slide.)

Now these are questions one through four. We recognize -- now you grappled all afternoon with what is research and here we are going to these agencies and saying not only decide what is research but put a number on it and put a dollar value on it, which was a

difficult task for many of them.

If you look at the first column, this is -- the first thing we did was to give us your agency budget in fiscal year '99 and that was an easy enough task for all of them.

We then asked them to then give us roughly -- we did not ask for exact numbers, they could not provide them, these are not -- this is not OMB quality data. We did not ask them to provide that.

Give us a sense of how much of your total budget is devoted to R&D and it is important that the R&D is sometimes counted in their number, sometimes it is not, some of them were able to separate out the D, others were not able to do that. So the second column there is the amount that they feel they devoted to R&D.

We then said of the amount that you devote to R&D about how much of that is devoted to research that involves human subjects and, of course, this was a very difficult answer for many of them to give us. Nonetheless, everybody did and we have a lot of caveats that we are going to have to apply to any interpretation of these data not the least of which is the difficulty that some of them had in defining exactly what constitutes research in their organization and what constitutes human subjects research.

But you can see that there is huge variability not only in terms of their total budget but I just did as an exercise this bar graph.

(Slide.)

I am sorry that it is not in color. My color printer was used to make many maps of China for a sixth grade social studies project and it ran out of ink.

(Laughter.)

DR. SHAPIRO: Good decision.

DR. HANNA: So it is not in color but I have good maps of the climate and geography.

I did this -- I just took six agencies. I just randomly selected them. Just because as kind of a civics lesson, I thought it would be a good idea to try and get a sense of perspective for some of these agencies. So the first column, which you cannot really see very well, and I know you cannot see it on the overhead -- I think you can see it better on the printout.

The first column is their total budget, the agency budget.

The second bar is the amount of their budget that is devoted to research.

And then the third bar, which sinks almost to the ground for many of these agencies, is the amount of

their research budget that is devoted to human subjects research.

The scales are obviously very different. I could not put DOD on here because then everybody else would have sank below the plane but it just -- I think it gives a good context. For some of these agencies their mission is quite different than for say CDC or NIH or FDA. The agencies that we typically think of as being kin of research based agencies.

If you look at, for example, Social Security's total budget and then go across and look at how much of it is human subjects research -- if you look at the VA you realize that so much of their budget is devoted to patient care and infrastructure, a large health services system, and that their amount of research that is being done with human subjects relative to their budget is quite small. So I think that is one -- one lesson.

I am not sure what you can interpret from it other than to realize that for a lot of these agencies in the grand scale their human subjects activities are relatively small compared to other activities that they are involved in.

(Slide.)

Going back to the survey, if we look at

questions five through seven, actually five through eight, these have to do with the really hard issues that you were grappling with this afternoon. How do you decide what is human subjects research? How do you determine whether something is exempt? Who determines that? Then on a little bit more quantitative side, do you have any IRB's in house? Those data are very dense and they do not lend themselves right now to any kind of quick summary but by the next time I report on this we will have a much better sense of where -- the answers are very complicated as you can imagine.

So I do not have anything to say about those right now. The only thing I can say from looking through these is that a lot of agencies struggle with determining what is exempt. Some of them have a very clear idea of what they think is exempt. Others might not agree with them that those are exempt and vice versa. So I think there is a lot of variability in what agencies determine to be exempt.

For example, you know, some agencies might consider a demonstration or evaluation project as being exempt. Another agency might look at the same project and not consider it to be exempt.

Some agencies because of their mission and their culture they consider some of their activities to

be exempt under the public benefit and service criterion, that it is part of their mandate, it is part of their mission to conduct -- provide the services that they provide.

They do not consider it necessarily to be research. If those same activities were being done in an agency that was not so service oriented they might be viewed differently. So I think there is just a lot of variability in the federal agencies.

For question nine it was fairly easy to characterize. We just asked them to please check off all the types of research that they are engaged in, whether they conducted themselves or whether it is conducted by contractors or through a grants program, and you can see that it is -- a lot of agencies are involved in a lot of different kinds of research.

I am not sure that we are going to learn anything from this other than that all of the categories of research are supported by several agencies.

(Slide.)

For ten, question ten, which focused more on vulnerable populations, I think that there are probably some surprises in here for some people and you cannot really take these responses at face value. I think a

lot of the agencies that are doing research in vulnerable populations provided fairly extensive explanation and documentation of exactly what those activities are and what the nature of those activities are.

Many of them who checked off, for example, research with pregnant woman said that, you know, that was a bit misleading of a question because the research might have had -- it had nothing to do with the pregnancy itself. It just so happened coincidentally that the woman was pregnant at the time that she was involved in the research. Or in some cases the woman became pregnant while she was involved in the research unbeknownst to the investigator.

So I think we have to be careful about drawing any conclusions from this kind of cursory look at the data. I think there is a lot more to it than meets the eye.

Interestingly, several agencies checked off in the other category that they do research or they sponsor research that is done with employees, contractor employees, parts of their work force, military personnel, students, and I think that they -- it was interesting that some of them characterized those as being vulnerable populations and they provided

pretty good explanations of why they did that. So I think there will be a lot that can be learned from what they have to say there.

(Slide.)

Some of the questions that we asked a little bit more about what their administrative structures are, that is how many FTE's do they have devoted to human subjects protections, how bit is the office, who signs off on decisions. There is huge variability, you know, based on what the departmental or the agency structure is and I am still struggling with what we are going to do with all of that information and whether it tells us anything.

I do not think there is any easy equation that if they do so many dollars worth of human subjects research that they should have so many FTE's or they should have so many IRB's.

I think one thing that you are going to have to grapple with is what I would call the hidden costs of protections for a lot of these agencies and that they might not have a lot of people in house but they structure a lot of their contract and grants programs to ensure that there is review but they do not do it. It is done by the academic institution or the research institution so a lot of the review is conducted outside

of their purview but with the assurance that it is being done so it is going to be hard to calculate whether -- you know, what the indirect costs are on grants or on contracts in terms of their review.

The only other thing that I would want to highlight are that the sanctions issue, which is addressed in 14, again is hugely variable depending on the agency as to whether sanctions include just having your laboratory taken away from you or being court-martialed. So the way that various agencies respond, most of them reported that they have not been in the situation yet where they have had to impose sanctions, and those that did described what the process was so I think that that will be useful information.

We asked some open ended questions at the end just to get a sense of where the agency thinks things are going. Question 16 asked them to describe any emerging research issues that are likely to influence human subjects protection and the list is there for you to see. I do not think there are any real surprises there.

I had to do some reading to figure out what action research is. I now know what that is. Where the -- the action research is where the people that are involved in the research actually participate in

modifying the design or altering the protocol in a certain way. I think it is used more traditionally in educational settings.

There were many more issues that were raised but I just thought these were some of the ones that were coming up over and over and mentioned by a variety of people. Research using large datasets, publicly available datasets, large databases using electronic communication, electronic information systems that were -- those issues were raised by a number of agencies. They are trying to figure out how to deal with those issues.

(Slide.)

Then the last one just asks -- we just said, you know, what issues are important to you and do you think that NBAC should be taking on. Again there should not be any surprises here. These are the same things that you have been talking about in your discussion. Clarification of, you know, what constitutes minimal risk, what is included under research, what is exempt, how to streamline interpretations across agencies.

Several agencies said that they co-fund some projects with other agencies and that there is a problem sometimes because the interpretation of the

protections in the federal guidelines say it might be slightly different and when they get -- when they go into co-funding situations those kinds of things have to be negotiated. People would rather that those differences did not exist.

Many agencies responded that they have growing concerns about research that is done outside of the purview of the federal system and there were many, many suggestions for kind of procedural administrative kinds of reforms that NBAC might consider having to do with IRB's, having to do with educational programs.

I think a lot of -- there were a lot of very good suggestions having to do with IRB's dealing all the way from, you know, judging competency and accreditation and accountability to instituting paid IRB's. So there was a lot of feedback there.

I think that probably -- I believe Marjorie has asked me to have a full -- kind of a full report available to the commission by July on this. I expect that we are going to have to go back to some of the agencies just for some clarification. Some of them provided interesting data. They responded in a way that I certainly did not anticipate and I think we are going to have to go back and just ask them to clarify.

If in looking at the survey again or the

survey instrument anything strikes you as being incomplete or if we are going to be in the process of going back -- and this would be in an interview manner -- to any of the agencies or if you have any particular agencies that you have questions about just let me or Marjorie know and we will try and follow up on that.

Any questions about what I have told you?

DR. SHAPIRO: Thank you very much, Kathi.

Alta?

MS. CHARO: Yes. One question concerning vulnerable populations. It is unfortunate that they found it difficult to answer because the question specifically asked about targeting those populations but some of them apparently answered any time a vulnerable person is included even incidently.

Were you able to tell from marginal comments that they scribbled which were which or if you go back to other reasons would it be possible to get an answer to the question that was originally asked?

I am only -- I am not saying that we should go back just for that but if we were going back anyway it would be helpful to have a sense of which agencies are targeting those populations and then have a sense of which agencies have adopted special protections so that we have a sense of where the protections are matching

up the populations. And, also, for those that did not if there is an absence of any problems it suggests that some of those special protections may not be needed any longer.

DR. HANNA: I think that is a good point and I am not sure from what we were provided whether we can discriminate between those that target those populations specifically and have special protections in place. I know some of the agencies -- for example, Department of Education, they have other -- they have either companion statutes like the Privacy Act or other countervailing kinds of regulations or statutes that they consider to be protective in another sense and we have -- we did get those kinds of data from the agencies but your question is a good one about the populations.

I was -- frankly, I was surprised at how many checks there were in those categories and I suspect that it is because they were including the fact that those populations were included in some research protocols even though they were not targeted.

DR. SHAPIRO: Diane?

DR. SCOTT-JONES: I pass. I answered it for myself.

DR. SHAPIRO: Pass.

DR. SCOTT-JONES: Pass.

DR. SHAPIRO: Kathi, maybe I could ask some questions. On the -- I guess it is the answers to 18. At least that is how it appears on -- which asks for suggestions. And they have clarification of requirements for protection for surveillance activities versus research.

Could you say a little more about that?

DR. HANNA: Well, I guess surveillance can be interpreted in a lot of different ways and without -- I have been trying very hard to not credit any particular comment to any particular agency at this point until we get some clarification from some of them.

I think surveillance is meant broadly in terms of collecting data on an ongoing basis perhaps in the CDC sense where there is surveillance activities underway in a population where you are trying to track the course of an infectious agent or whatever.

I do not think it is meant in the sense of the -- you know, kind of the watching people in -- observing people that are unaware of the fact that they are being watched but I think that the surveillance activities where people are just collecting data over a period of time because they do not know what they are looking for but they suspect something is going to come

up out of the data that is going to give them a clue as to what is going on, I think agencies that do that kind of work do have a problem with understanding how that kind of research should be reviewed.

DR. SHAPIRO: Could you -- I understood what your response was to really focus on what I would think was sort of public health activities. They are trying to protect the public, therefore they are watching the progression of something out there. And that is different, for example, from the government, for example, evaluating or the HMO evaluating how well the HMO is doing by surveillance of that kind or the HMO doing it for itself for its own quality control purposes.

It is mainly the former that is at stake here in the response that you have gotten and not the latter?

DR. HANNA: I think so although I think surveillance, for example, from some of the agencies that do health services research, they do -- they might be doing some kinds of surveillance on quality indicators from a variety of health care sites. They might be just trying to monitor outcomes for certain diseases in certain areas. And so I think they struggle with whether that is doing human subjects

research and whether that has to go under IRB review or whether they are fulfilling some kind of a congressional mandate that this be a part of their activity so that they can design services that -- I mean, it is -- you are seeing it in the news right now with what the Census Bureau has been struggling with.

When is it just collecting information that is going to help an agency provide services, which is their mission, versus conducting research and I think it is a problem that seems to haunt several agencies.

DR. SHAPIRO: Given the current definition I can understand why. It is not -- at least it is not clear to me.

Could you say something also about the triage system to determine risk? I could not quite understand what you meant by that?

DR. HANNA: Well, a couple of different agencies mentioned the fact that they think that there should be some kind of a system where you can quickly determine, you know, a level -- I guess it is a modification of the expedited review which several of them said does not make things go any faster necessarily but a system where there could be a quick determination that something is minimal risk or it might not warrant IRB review where it could quickly get

moved into a category of scrutiny depending on whether it needs a high level of scrutiny with everybody on the IRB reading the protocol and actually physically meeting and talking about it versus something much faster.

I think it is probably they are referring to some kind of a variation on expedited review. There is a sense out there that expedited review does not do what it is supposed to do.

DR. SHAPIRO: Yes. And under the bullet that deals with administrative reforms, have they come up so far -- you may not have gotten this far with what you think are some useful and creative suggestions in this area because it is obviously an area of concern for everyone, and I just want to see if you are sort of getting some useful suggestions other than just, you know, do something.

DR. HANNA: Well, I think that they have -- there were some suggestions that came up as to how there could be reforms in the federal oversight system having to do with issues having -- like location of OPRR. What this new office should be doing and what its mandate should be.

So there were some useful suggestions there. There were also some suggestions about how agencies can

or should interact with IRB's and what the record keeping and reporting mechanism should be.

I have to say, though, that I do not think that agencies for I think obvious reasons were forthcoming about changes that they think might be made in their own organizations, and I think that that is understandable.

These surveys had to go through several layers of review and sign off and we did not really ask them, to be fair, to focus too much on what could be done in their own agency. We did ask them to report on what changes have occurred in their agency over the past three years and we have got a lot of information there.

DR. SHAPIRO: Some of the -- oh, Steve?

DR. HOLTZMAN: Well, if you are in a line of questions go ahead, Harold. I do not want to interrupt.

DR. SHAPIRO: I just have one small question. One of the issues was coordination -- I have forgotten where this is. It was something to do with coordination and differences between agencies and so on, something of that nature.

And one of the things that we hear a lot but has never really been clarified was the relationship between the NIH and the FDA, and whether that was

adequately coordinated and so on even though they have some different regulations that apply. Was that the issue they were referring to or is it just another set of issues all together?

DR. HANNA: I would have to say that that is probably the primary tension point for -- not just for NIH and FDA but for other agencies that kind of get caught in the confusion.

DR. SHAPIRO: Yes. Okay.

Steve?

DR. HOLTZMAN: I am not sure this is a question for Kathi so much as it is for the commission. If one takes on its face this $10.6 billion number you cannot help but be struck that plus or minus NIH represents 81 percent of it, HHS represents 87 percent of it, and HHS plus the Census represents 93 percent of it.

What does that suggest, if anything, to us about where we should be focusing our energies in terms of concerns about regulation and where the system needs to be beefed up and what kinds of research? Or is the answer it does not at all and any single human being in any form of research deserves protection.

DR. SHAPIRO: Eric?

DR. CASSELL: Well, I think that if we look

back at the issues that have been -- that have made problems, partly to which we are responding, they did not all occur in those big places. I think it is just -- it is everywhere and it has to be everywhere.

DR. SHAPIRO: That is my own feeling as well, Steve, although obviously if you put NIH or HHS and include FDA in that and sort of sweep in all the things that come through that, which are not on this -- which are not on this page that is a huge -- that is a huge majority of the work that is actually going on. It is very large. And so I think that is a helpful and useful piece of information to keep in mind but I do not think we should for the reasons Eric suggested ignore the other.

Larry?

DR. MIIKE: Maybe it is too soon to answer but was there a qualitative difference in the response for possible changes between say NIH heavily into biomedical research and the other agencies which are scattering just about everything else?

DR. HANNA: Let me understand -- try to understand your question. You mean did they -- the response - the open ended question as to kinds of problems that are occurring -- the agency -- well, NIH and FDA had a lot to say there but I think that --

DR. MIIKE: I guess --

DR. HANNA: I think that some of the interpretive issues having to do with the Common Rule are much more problem -- were much more problematic for the nonbiomedical agencies. I mean, the real puzzlers for them in terms of what qualifies as research and what is exempt and what is minimal risk, I -- it -- just on face value those kinds of concerns seem to be much more on the top of the list for the nonbiomedical research agencies.

DR. MIIKE: Okay. I guess, for example, being the Bureau of Census and NIH would be one example.

Can I just ask just one question on the Bureau of Census? It seems that they have just about said everything they do is research and I would not buy that. They put the whole -- they put their whole budget in as research and then they put about half of that as human subjects research.

DR. SHAPIRO: You mean in the table that is here, yes.

DR. MIIKE: It is just a comment by me. You do not have to answer it but I just -- I just thought I would not agree with that.

DR. SHAPIRO: Yes, I understand. I understand.

Other questions? Any other questions for Kathi at this time?

Kathi, what is roughly your time frame here for progress? I understand -- I know there is lots and lots of paper to go through so I am not trying to --

DR. HANNA: Well, I think I am still -- I am still having discussions with Marjorie and Eric about what is the most useful way to present all of this information.

DR. SHAPIRO: Yes.

DR. HANNA: I think that we have to figure that out first and obviously any suggestions any of you have would be very helpful. Marjorie and I have talked about using examples that come out of this survey data throughout the report. For example, there are some excellent educational programs that are supported by some of the agencies for IRB's and whatever that I think would be useful models.

I think we have to figure out whether you want to see all this data reported in one place or not. If you do then the schedule would be that by July that would be in a final report.

Do you have a preference for seeing it all in one place or just kind of mining it as needed?

DR. SHAPIRO: Well, I think I, myself, do not

see it all in one place if you are asking me the question. I just really want to see what the key inferences are and have the back up where that is necessary but not necessarily all in one place. That is just my view.

Okay. Any other questions before we adjourn this session and this afternoon's meeting.

Okay. Thank you all very much.

(Whereupon, at 4:56 p.m., the proceedings were adjourned.)

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