28TH MEETING OF THE SECRETARY'S ADVISORY COMMITTEE ON HERITABLE DISORDERS IN NEWBORNS AND CHILDREN

Thursday, September 13, 2012

AFTERNOON SESSION

1:30 p.m. - 2:15 p.m.

Humphrey Building

HHS Headquarters, Room 800

200 Independence Avenue, S.W.

Washington, D.C.

APPEARANCES

COMMITTEE MEMBERS:

JOSEPH A. BOCCHINI, JR., M.D.

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CHARLES HOMER, M.D., M.P.H.

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KELLIE B. KELM, PH.D.

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SARA COPELAND, M.D.

APPEARANCES (Continued)

ORGANIZATION REPRESENTATIVES:

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FREDERICK M. CHEN, M.D., M.P.H., F.A.A.F.P.

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MARY J.H. WILLIS, M.D., PH.D.

C O N T E N T S

CHAIRMAN BOCCHINI: All right. Let's go ahead and call the meeting to order.

(Pause.)

CHAIRMAN BOCCHINI: All right. Thank you.

We're going to start the afternoon session with a discussion from -- on ethical issues, ELSI and the Advisory Committee. Jean McEwen. Am I close? Close enough?

DR. MCEWEN: McEwen.

CHAIRMAN BOCCHINI: Who is Program

Director of Ethical, Legal, and Social Implications Program at the NHGRI/NIH, will make this presentation.

Dr. McEwen came to the National Human Genome Research Institute in 1999 following a career in law practice teaching and research. In her capacity as program director, she currently manages a portfolio of research grants focused on the ethical, legal, and social implications -- that's the ELSI -- of genomics research and related policy issues, as well as the cooperative agreement for the conduct of large public consultation study to obtain public input to inform the design of a possible large longitudinal cohort study of the role of genes and environment in health and disease.

She also currently manages a consortium of investigators conducting research on normative legal and psychosocial issues surrounding the return of genomic research results.

So we really appreciate you taking the time to come here and make this presentation. This is very important to the committee. So thank you.

DR. MCEWEN: Okay. Thank you. And thank you very much for inviting me. I found this morning's session very interesting. It's my first time attending one of these meetings.

So I was asked to talk today about -- a little bit about our program, not so much really about the substantive ethical issues that I see on the horizon in the field of genomics, but actually about the way that our program at the National Human Genome Research Institute operates and the kinds of opportunities that we have for grant funding and so forth.

My talk is going to focus very generally on our program and not specifically on newborn screening. My understanding is that we will have a more specific focus on newborn screening -- on ethical issues and newborn screening at the January meeting.

So this is going to be very generic, and I should say perhaps even more generic than I had intended because I just realized just before lunch that the slide set that I sent was actually not the

one that incorporated my revisions that were geared specifically for this group. So I'll try to, as I go along, bring in the particular context that's specific to this group. But I do apologize for the overly generic nature of some of this.

So I think what we'll do is we'll start. I'll give you a brief background about our program, talk a little bit about the latest strategic plan for genomics and specifically for approaches to studying issues about what we broadly now are calling genomics and society within our institute.

Talk a little bit about current high-priority topic areas that we're supporting research on in our program, a little bit about the methodological approaches and kinds of funding mechanisms that we use. I'll say a few words about our program in Centers of Excellence in ELSI Research, or our CEER program.

And then say a little bit about some of the specific and kind of unique sorts of challenges and tensions that we sometimes confront in doing this kind of research, which is really in some ways

quite different from other kinds of research that's typically supported at the NIH.

So by way of background, our program was established in 1990 at the same time that the Human Genome Project was first launched. And its mission was -- always has been to anticipate and attempt to address the ethical, legal, and social implications of genetic and genomic research. So that's the term ELSI that's become kind of a commonly applied acronym for this area of research, and our program is commonly known as the ELSI research program.

So since the beginning of the Genome Project, the NHGRI has devoted every year 5 percent of its extramural research budget to support research on these kinds of topics, and I'll talk in a little bit about the specific kinds of studies that we've funded over the years. Our budget this fiscal year is around $19 million. And over the 21 years that we've been in existence, we've supported a large number of studies, now numbering over 1,000 publications resulting from that work.

So it's really a fairly large body of

scholarship that's been amassed over the years. And I think it's fair to say we're still considered the largest funder of bioethics research in the world.

Just to sort of situate our program within the larger field of genomics and within NHGRI specifically, a lot of you probably have seen this, and if you haven't, I would actually commend it to you. This was sort of a we call it our strategic plan for the future of genomics research. It was published about a year and a half ago in Nature following input from hundreds of -- well, yes, hundreds of people, I would say, including both genomics researchers and also a lot of people from the social sciences and bioethics, who are sort of, again, looking ahead to the kinds of ethical, legal, and social issues that this field is going to be confronting increasingly over the next several years.

And so, just to dig into this plan a little bit, this is sort of a schematic that sort of shows where we see the field of genomics as it has been evolving and as we anticipate that it's going

to be evolving over the coming years. There's a lot of information in this slide. But just to kind of briefly explain to you the main features, what you see here at the top are sort of five almost you can think of sort going from the left to the right as sort of a movement in orientation in the field.

Starting with at the very beginning of the Human Genome Project, when we were really focused on sort of understanding the structure of the genome or actually more accurately genomes because we were also obviously interested in studying a lot of model organisms. Then gradually, we began to look more and more at sort of understanding the biology of genomes. The biology of genomes, not just the structure of genomes.

And so, for example, at the Genome Institute, we've run a number of projects. For example, the HapMap Project and the 1,000 Genomes Project, which are looking at patterns of genetic variation in a number of populations around the world to develop these large genomic resources that can really help us to start to understand the basic

biology not necessarily focused on disease, but just really what the genome is made of and what some of the functions of these parts of the genome might be.

Gradually, we are moving into -- more and more into understanding the biology of disease, and this is -- certainly for the NHGRI, this is a much newer area. But it's obviously an area in which other parts of NIH have been focused for some time. But what we're hoping to do is to help to actually help other institutes to understand how to incorporate specifically genomic approaches into understanding the biology of disease as they do their studies.

And gradually, and this is only now at the very beginning stages, are we moving way to the right in sort of advancing the science of medicine, and ultimately, the ultimate goal is improving the effectiveness of healthcare. But you'll notice that we don't envision that as being a goal that's anywhere near completion and probably won't even really get well underway until well beyond the year 2020.

So we're trying to be not overly promising in how quickly we think these technologies will move. But at the same time, recognizing that there actually has been a fair amount of progress and that, ultimately, our goal is to get over to that sort of right-hand side of the diagram.

One of the things you'll notice when you sort of think about this is over on the left, when we were initially with the Human Genome Project just sequencing that one human genome and looking at a variety of model organisms, we didn't have to worry a whole lot about issues about protecting participants in genomic research because we didn't really have any. We were just sort of doing the first genome.

But increasingly -- we obviously didn't have to worry about ethical issues with mice or rats too much. I mean a little bit. But we didn't have to worry about things like privacy or informed consent because they were mice and rats.

But increasingly, as we move further and further to the right side of this diagram, you can

see how interactions with patients and research participants and, in fact, with the general public and helping them to understand the meaning of this sort of avalanche of information that we're creating becomes increasingly important. And that's where the ethical issues are becoming much more complex over time.

And so, in recognition of this, I think there is sort of a recognition that sort of this broad rubric of genomics and society or ethical issues really cuts across all of these areas, and it's going to become increasingly important in the future.

And so, within this sort of broad rubric of genomics and society, there are sort of four sets of issues that you can think about as being ones that we're going to have to grapple with -- psychosocial and ethical issues in the research, the same kinds of issues in genomic medicine, and then sort of broader legal and public policy issues, and then even broader societal issues that go even beyond that.

And so, what I want to do is talk to you a little bit about the kinds of specific research topics that we've tended to support in each of these areas and the kinds of things that we're interested in looking at down the road.

So, in the first category, psychosocial and ethical issues in genomics research, here I've just sort of arbitrarily listed a couple of research topics among the many, many that I might have chosen. And the first one is so broad that it's almost meaningless without sort of digging into it a bit more, and that's protection of research participants.

So these are old issues relating to things like privacy and informed consent. And increasingly, issues about whether, when and how, and how much to return to people in terms of the results that we generate in the research, particularly the incidental findings.

Which once you start sequencing whole genomes, inevitably you're going to create a lot of those. What do you do with that? What do you do

with that kind of information, and what are the ethical issues involved?

Perceptions of risks and benefits in this kind of research. This is an area that I think is becoming more and more complicated as sometimes the line between research and clinical care becomes increasingly murky as we start to move sequencing or whole genome technologies into these clinical settings and sometimes research settings.

And then other issues like how do we ensure the diversity of our research cohorts to make sure that all segments of society have an equal opportunity to participate in the research? The role of race and ethnicity, which has always had kind of an uncomfortable relationship between -- with the field of genetics. How do we develop our constructs of race and ethnicity, and how do we incorporate those when we conduct research looking at allele frequency differences among groups? And what are the ethical issues that that are raised?

And certainly, community engagement and community consultation has been a big issue in

recent years as we start to do this kind of research. Sometimes this kind of research raises issues that pertain not just to individuals, but to broader communities. And so, what are the issues involved with doing that?

Just very quickly, to talk about some of the issues, specific topics in the genomic medicine area. Probably the biggest one that really permeates so much of so many of the others is the whole issue of how we deal with genomic uncertainty and how we convey to research participants and patients and, in fact, to the public that the information that we're generating is still very uncertain? And how do we help them make sense of the risk estimates that we're providing? A lot of complicated ethical challenges there.

Another area emerging is direct-to-consumer testing. What are physicians to do when someone shows up in the office with a printout from 23andMe showing their risk status for 63 different conditions? What are they supposed to do with that in the 20 minutes that they have available for the

appointment?

How do we ensure fair access to these technologies? This is sort of analogous to the issue about ensuring fair access to participation in research. How do we regulate diagnostics, therapeutics? And how do we ensure that the information that we're generating is actually going to lead to some kind of behavioral change?

For example, someone learns that they're at increased genomic risk for hypertension or heart disease. Are there strategies that we could use to make sure that people understand that information in a way that tells them I've got to eat better and exercise more rather than using it as an excuse that, well, I'm going to get sick anyway. I might as well go have a hamburger. This is a big challenge.

A lot of issues related to pre-implantation, prenatal, and post natal genetic diagnoses. Obviously, this is where newborn screening comes in. But there are obviously new technologies on the horizon. Recently, there has

been discussion about noninvasive prenatal whole genome sequencing.

And one can imagine -- this is from maternal blood. One can imagine if that actually becomes something as widely available, the slew of ethical issues that that could raise about how people are going to use those technologies and the potential for attempts at genetic enhancement and those sorts of things.

And once again, constructs of race and ethnicity and how conceptions of racial differences will play into genomic healthcare. Another big and largely unexplored area that we're very interested in supporting more research on.

In the legal and public policy area, again, I've just picked out a couple of issues, but there are a large number of these. Intellectual property issues, gene patenting.

A lot of you are familiar with the Myriad Genetics case that now is sort of bouncing around in the courts, and it's unclear how that will finally be resolved. But even when it is resolved, there

are always going to be new intellectual property challenges in this area.

Issues about access and insurance reimbursement will continue to come up. Regulation of genetic testing, including direct-to-consumer testing. The new pharmacogenomics and therapeutics will be issues.

Genetic discrimination and stigmatization issues, which one many people had hoped would have been resolved back I think in 2008 when we saw the passage of the Genetic Information Nondiscrimination Act.

It turns out that most people either never have heard of the law, or we now have research that shows that even if they know about it that they don't really have much confidence that it's going to have much effect. So what does that mean? And where are these issues still live?

Related to this is the many potential applications, some of which we're already seeing, of genetic and genomic information in nonmedical settings, such as obviously insurance and

employment, but even in areas like education, sports, and obviously many forensic uses. Ancestry, DNA ancestry testing is becoming a big issue now, and this raises a lot of issues about how this information is going to be understood and used.

We also have always had an interest in supporting research on what we call sort of broader societal issues, and a lot of this is research that some people kind of see it as being frivolous. But it's actually really important in some ways.

This is largely research on issues that are somewhat philosophical, but actually are the big questions like how does research and our changing conception of genomic information alter potentially our concepts of health and disease or what it means to be normal? Concepts of individual and group identity. Insights on human origins and evolution.

And then another big area, genetic determinism, free will, and individual responsibility. This is the area of behavioral genomics that has always been with us, but as this research continues I think will pose a lot of

questions for how we understand sort of free will. So we support research on these kinds of questions as well.

Just to talk very briefly, a lot of our research is highly interdisciplinarian, or at least multidisciplinarian. This slide, which I won't go over in detail, but shows kind of the range of disciplines of the various researchers that we supported over the years come from, and you can see that we support a lot of people in the social sciences and in bioethics and in fields like, obviously, legal analysis, public health, health services research, and a number of these fields.

And using really a whole range of methodologies, some of them sort of standard empirical research. You know, doing either experimental designs or surveys. Some of it more qualitative. Focus groups, interviews. And then, historical research using archival methods, ethnographic methods with some of our anthropology studies. So it's really a wide range of methods that's really produced a pretty rich set of

scholarship.

And this slide just shows, just based on a kind of study of our grants over roughly the last 5-year period, that almost half of the studies that we've supported actually involve the use of multiple methods, although some are single method, either quantitative or qualitative or a small number of purely legal studies or what we call conceptual studies. These tend to be studies by philosophers and so forth on more -- some of those broader sort of philosophical issues.

Just a slide showing our Web site, where you can actually access a nice sort of searchable database that shows not only all the studies that we funded over the years, but will provide information with the citations to the major publications that have come out of each one. And this is searchable by the investigator or by topic.

So, for example, if you were interested in finding just what we've supported in the area of newborn screening or, say, more generally, in pediatric issues, you could put in those kinds of

search terms, and the stuff would come up.

Just very quickly, we use a range of funding mechanisms. I've listed the most common ones here. We support a lot of regular NIH R01 regular research grants, but also smaller grants, R03s and R21s, for those of you who are familiar with the NIH nomenclature.

We occasionally support conferences that are looking at these kinds of issues, and we support training grants like postdoctoral training grants and career development awards. And then we also have administrative supplements that we make available sometimes when people come into unexpected problems in their research and need additional funds or supplements to bring in new minority researchers.

Because one of the things that we're really actively trying to do is to increase the participation by people from underrepresented minorities in doing this kind of research because we think it's really important to make sure those voices are represented in the scholarship because they're such an important part of the research.

We tend to use sort of a mix of approaches to funding. Most of our grants have tended in the past at least to be investigator initiated. But we do occasionally issue a request for applications to address particular important emerging issues.

Some of the ones that we've done in the past relate to carrier screening for cystic fibrosis. We did a large consortium back in the '90s on cancer genetics testing, which was actually pretty influential in influencing the way we think about a lot of the ethical issues related to testing for other kinds of complex diseases.

We did a consortium focused on ethical issues in genetics variation research and related to issues around race and ethnicity. And currently, we have a very active consortium going looking at these very complicated issues about returning results and incidental findings.

So what we do when we issue these RFAs typically is we'll put the researchers together in a consortium where they can meet together to talk about what they're doing and share their instruments

and measures and try to see if they can develop -- ideally to come to consensus and develop joint papers. That's worked better in some of these consortia than others, depending on the nature of the topic.

We also occasionally fund RFAs sort of in parallel with other large genomic projects that are going on either at NHGRI or across NIH. Two recent examples where we put out an RFA related to the ethical issues raised by human microbiome research because some of you are aware there's a large common fund project at the NIH called the Human Microbiome Project that's looking at the role of the human microbiome in health and disease. And so, looking at the various ethical issues that's raising.

And then a new one out just recently looking at or in connection with our H3Africa Program, which is really focused on genomic research in the African subcontinent and really looking at or trying to get African researchers directly involved in studying these issues.

We also -- more recently, an important

approach has been to actually incorporate or require that researchers incorporate investigation of these ethical issues in larger genomic projects like right now we have a consortium called the eMERGE Consortium that's looking at incorporating genomic information in electronic medical records. And also a clinical sequencing exploratory research consortium that, again, is looking at incorporating genomics into clinical care.

And so, what we've done in these cases is to actually put an ELSI component right into those RFAs so that anyone who wants to apply for one of those RFAs has to have people on their project team who have this expertise in looking at the ethical issues and actually propose research on those issues. And when these projects are reviewed, we look at the ethics component as being equally important as the more basic science component.

So that if a project does just well on the basic science, but kind of ho-hum on the ELSI part, it doesn't get funded. And so, we're probably going to be doing more of those in the future.

I wanted to say a few words about our Centers of Excellence in ELSI Research program. This program was launched in 2004 with three goals. We sometimes call them the three Ts because it's we want to foster transdisciplinary research, facilitate the translation of the research into specific health research and public policies, and we want to focus on training the next generation of researchers in this area.

And so far over the years, I think we've trained -- or I should say the centers have trained over 80 younger researchers, of whom I believe more than 30 have been members of underrepresented minority groups. We currently support six of these, or six full centers, plus two exploratory centers that are preparing to perhaps potentially put in applications to become full centers in the future.

These centers are at, if I can list them all, there's Stanford, Case Western, UNC, University of Washington, Penn, and I'm blanking out the sixth one. Sorry? Oh, I thought you were going to help me out.

In any case, they're on our Web site. We have two others. One at Columbia and one at Oregon Health Sciences University. Each of these is focused on sort of a different specific topic or set of topics.

For example, one of the centers is looking at ethical issues in epigenomics and epigenetics research. Another one is focused specifically on intellectual property issues. Another one is looking at issues in behavioral genetics.

So these are really very focused centers that are, again, really trying to bring together people from this whole range of disciplines to have them really look at these issues comprehensively and then actually try to go out and help to translate some of those findings into policy or practice by going out and actively being on advisory groups, providing expert testimony.

In some cases, they've written amicus briefs to courts on particular issues and those kinds of things. So it's really a kind of translating the research to policy that we're trying

to push through these centers.

Just a few things I'll say about some of the tensions that we have in our program and tensions in funding this kind of research. I think there is always a tension between how much we want to focus on or encourage people doing very sort of basic, fundamental ethics research and how much we want to focus on more policy-focused research or research that's really focused on sort of translation.

There is sometimes a tension between those things, and related to that is a tension between how much we should be sort of top-down trying to initiate versus how much of this should be investigator initiated.

I think a related tension is sometimes our researchers, because they are -- they really do become the experts in the field, are called in by genomics researchers to provide consultation in connection with the projects that are going on at their institutions. Obviously, a good thing, but sometimes not only does that sort of detract from

what they're doing in the research, but it occasionally leads to a situation where sometimes people feel that they're almost at risk of losing a bit of their objectivity and independence and potentially even becoming what some people think of as being handmaidens to the research.

So there's always a little bit of a tension with that. But it's one that I think so far most of our investigators have managed to navigate pretty well.

So just sort of looking into the future, I think what we're going to need to do is sort of re-envision some of these tensions I've mentioned as really opportunities. Really think about how creatively can we get this kind of ethics and law and policy research to really influence the research without becoming sort of beholden to it.

Another big challenge for us, obviously, is going to be figuring out how we're going to address setting of priorities in this very uncertain funding climate. As you know, we're facing potential pretty serious cuts over the next couple

of years. so we're going to have to do some heavy duty prioritization.

At the same time, we want to sort of expand the research and better integrate it. But obviously, all that costs money. So I think priority setting is going to be a big challenge for us in the future.

We actually are just now in the process of setting up a working group that's going to help us to advise us on some of these priorities because, obviously, we're not able to do everything and do it well, or at least not as well as we have in the past without greatly increased funding because our mandate is just becoming broader and broader as we move to the right of that diagram that I showed you earlier.

So I think that's really all that I have, but if people have questions, I'm happy to take them.

CHAIRMAN BOCCHINI: Thank you, Dr. McEwen, for that very good presentation.

It's open for questions and comments.

Dr. Botkin?

DR. BOTKIN: Jean, I wondered if you might comment on how some of the other NIH agencies have collaborated with the ELSI program over the years? I mean, it was borne out of the Genome Institute, but some of the other institutes have been collaborating over time with some of the research initiatives.

DR. MCEWEN: Yes. We have had collaborations, and we have a number of other NIH institutes have signed onto our sort of standing program announcements that we have that are sort of standing announcement that we have that are not specific calls for applications, but that just are sort of out there for people to come in at any time with applications.

I can't remember exactly how many institutes are signed on currently, but it's a good number. Probably at least eight or nine, one of which is Child Health. And I should say that with Child Health in particular, we've actually had quite a number of joint initiatives in the past, including

-- and I don't want to get into this in any kind of detail, but I think most of you are aware of it -- that currently we have an RFA out on specifically looking at newborn screening.

Actually, it's a more general RFA, but it's one of those ones where, as I talked about, embedding the ELSI research in the genomic research, and this is one of those where there actually is an ELSI component. And NHGRI and NICHD are working very closely together on that one.

DR. GUTTMACHER: Maybe just a follow-up to that, since Jeff brought it up and since I used to be the Deputy Director at the Genome Institute and now direct another institute.

It has, I think, been -- when I was at the Genome Institute, it was somewhat of a frustration that while other institutes did sign on to certain projects and helped fund certain projects, et cetera, that nobody seemed to be replicating the idea. That is, saying, gee, this is so compelling that we should have a set-aside and/or simply a focused effort at our place to look at ethical,

legal, or social, or whatever anybody would want to title it, implications of our own research.

And I think you can see pockets over here and there at other NIH institutes and, in fact, in other Federal agencies. But it has not been, for whatever reasons -- and now that I wear another hat, I see it from a slightly different perspective, I suppose. But it is not something that has been imitated as widely as I think some of those back at the creation had hoped.

I think it's been very effective, but not so effective at borning itself again, you know?

DR. MCEWEN: Yes, I think that's right. And there has been a lot of talk for the last several years about actually trying to implement some kind of a bioethics initiative, sort of trans-NIH large bioethics initiative.

And I think there's a lot of people who are interested in doing that, but I think right now the funds just aren't there. And so, this just always tends to fall kind of unfortunately to the bottom of the list of priorities.

But it is unfortunate because it is very clear that our program can no longer be it for all of the other NIH institutes. There are just too many issues that are coming up that are in some ways kind of disease specific, and that really ought to be the responsibility of the other institutes. We cannot do it all, as we've tried to in the past.

DR. PARISI: This is Melissa Parisi, and I just wanted to echo what Dr. McEwen said and Dr. Guttmacher and make sure that this audience is informed about this current RFA that is on the streets and is a partnership between the National Institute of Child Health and Human Development and the National Human Genome Research Institute.

And it is entitled Genomic Sequencing in Newborn Screening Disorders, and the two institutes have worked very hard to make sure that there are three components that are included within this RFA, and any successful applicant needs to include not only the genomic approaches and careful consideration of that, but also the clinical implications of this sort of genomic approaches to

newborn conditions as well as an ELSI component.

So we see this as an important potential addition to the dialogue around these ELSI-related issues and genomics and newborn screening.

CHAIRMAN BOCCHINI: Thank you.

If there's no questions, comments?

DR. HOMER: Again, this may be another cart before the horse question if there is an RFP out on the street. But I guess delving substantively, are there findings or recommendations from the research that have been done that should be incorporated, for example, into something like the matrix that we just reviewed this morning?

In other words, should there be checklists? Should there be ethic -- I mean, how should we incorporate the recommendations from the research that's been done to date in our decision-making about whether and when to introduce a new screening test onto the list of required screening procedures?

What are the ethical issues in delaying consideration for an evidence review? So, anyhow,

again you described the program and what it covers. But I'm just wondering, substantively, are there -- is there sufficient clarity from the previous research to date that would inform our ability to make decisions or --

DR. MCEWEN: You know, I think we actually have supported a fair amount of research on these kinds of issues in newborn screening. But it certainly is not -- we don't have the answers, by any means.

What I would suggest that you do is take a look at our Web site, and you can access most of the papers that have been published on this. And they certainly do speak to a lot of these issues. But I think certainly Jeff knows more than anyone that this remains an area where we don't have the data that will help us to answer all these questions.

And some of these questions aren't purely data driven. Some of them incorporate normative considerations that are the kinds of things about which there is never going to be complete consensus.

CHAIRMAN BOCCHINI: And then, in addition

to that, I think the presentation that we are planning for January is going to focus more specifically on newborn screening, ethical issues surrounding newborn screening. And so, I think we're going to address these in a more specific manner.

But I think your point is really an excellent one that the data that's available needs to be incorporated into the decision matrix process. I think that's a very important point.

All right. Other questions or comments? If not, thank you again for a very excellent presentation.

DR. MCEWEN: Thank you.

(Applause.)

CHAIRMAN BOCCHINI: So we are about 15 minutes early. So I think that the plan ought to be that we take a 15-minute break. But instead of starting the subcommittee meetings at 2:45 p.m., we can actually start them at 2:30 p.m. So we'll go ahead and do that, and then you have a couple of housekeeping things?

DR. COPELAND: Yes, a couple of housekeeping things. You have to be done with your subcommittee by 5:00 p.m. because we have to pick up after and reset the rooms. So people need to be cleared out by 5:00 p.m.

I'm speaking to the Follow-Up and Treatment Subcommittee.

(Laughter.)

DR. COPELAND: Yes. Yes. Just so you know.

And just good general politeness, manners. Clean out your garbage with you on your way out of the room, please.

CHAIRMAN BOCCHINI: Okay. All right. So a couple of other things. Just to remind you of the rooms.

Let's just review the rooms. The Laboratory Standards and Procedures Committee -- Subcommittee will meet in Room 305A. That's on the third floor. Follow-Up and Treatment will remain here. Education and Training will go to Room 425A, which is on the fourth floor.

Now each of the groups needs to be escorted to the room so that people will meet you at the doorway to bring you to those various places.

Lastly, for the committee, there is no formal dinner set up for this meeting because a number of the people from the committee are committed to an event tonight, which is honoring Dr. Howell. But those of you, if any of you would like to meet, if you'll meet with Maureen out front, we can get a group together, if you'd like to go out to dinner together.

All right. Then we'll see you bright and early tomorrow morning.

Thank you all very much.

(Whereupon, at 2:15 p.m., the meeting was adjourned.)