

Privacy & Security Tiger Team
Draft Transcript
September 9, 2011

Operator

Ms. Sparrow all lines are bridged.

Judy Sparrow – Office of the National Coordinator – Executive Director

Thank you operator. Good afternoon everybody and welcome to the Privacy and Security Tiger Team. This is a Federal Advisory call so there will be opportunity at the end of the call for the public to make comments. A reminder Workgroup members please identify yourself when speaking. A quick roll call. Deven McGraw?

Deven McGraw – Center for Democracy & Technology – Director

Here.

Judy Sparrow – Office of the National Coordinator – Executive Director

Paul Egerman?

Paul Egerman – Businessman/Entrepreneur

Here.

Judy Sparrow – Office of the National Coordinator – Executive Director

Latanya Sweeney? Gayle Harrell?

Gayle Harrell – Consumer Representative/Florida – Florida State Legislator

Here.

Judy Sparrow – Office of the National Coordinator – Executive Director

Carol Diamond? Judy Faulkner?

Judy Faulkner – EPIC Systems Corporation

Here.

Judy Sparrow – Office of the National Coordinator – Executive Director

David McCallie?

David McCallie, Jr. – Cerner Corporation – Vice President of Medical Informatics

Here.

Judy Sparrow – Office of the National Coordinator – Executive Director

Neil Calman? David Lansky? Dixie Baker?

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

I'm here.

Judy Sparrow – Office of the National Coordinator – Executive Director

Alice Leiter?

Alice Leiter – National Partnership for Women & Families

Here.

Judy Sparrow – Office of the National Coordinator – Executive Director

John Houston?

John Houston – University of Pittsburgh Medical Center – NCVHS

Here.

Judy Sparrow – Office of the National Coordinator – Executive Director

Wes Richel? Richard Platt?

Deven McGraw – Center for Democracy & Technology – Director

He'll be joining us at 3:00.

Judy Sparrow – Office of the National Coordinator – Executive Director

Okay. Sean Grannis? Leslie Francis?

Deven McGraw – Center for Democracy & Technology – Director

Yeah, Leslie's in Scotland.

Judy Sparrow – Office of the National Coordinator – Executive Director

Okay. Lisa Tutterow?

Lisa Tutterow – Office of the National Coordinator – Executive Director

Here.

Judy Sparrow – Office of the National Coordinator – Executive Director

Did I leave anyone off?

Joy Pritts – Office of the National Coordinator for Health Information Technology – Chief Privacy Officer

This is Joy Pritts.

Judy Sparrow – Office of the National Coordinator – Executive Director

I was just getting ready; you're at the very bottom of this list Joy.

Joy Pritts – Office of the National Coordinator for Health Information Technology – Chief Privacy Officer

Okay.

Judy Sparrow – Office of the National Coordinator – Executive Director

Joy Pritts. Now I'll turn it over to Deven and Paul.

Paul Egerman – Businessman/Entrepreneur

Thank you very much, this is Paul Egerman, I want to thank everybody for participating in our Tiger Team Meeting on this Friday, Friday afternoon, except out on the west coast where I guess it's late morning, but your participation is very much appreciated and as Judy Sparrow mentioned there will be a time at the end of the call for public comment for members of the public to give us their feedback and that feedback is extremely important. And we have a very interesting topic that we want to try to make some good progress on today which relates to an ANPRM, Advanced Notice of Proposed Rule Making related to the Common Rule and the secondary uses of data and so it's a very interesting discussion, but also a little bit unusual. But, before we get started usually I thank people at the end, but I just wanted to take a moment and make sure right at the beginning of the call that I say thank you to Judy Sparrow. Judy is retiring at the end of September and has really done a phenomenal job for this Tiger Team for the Policy Committee, and also, you know, I just want to say thank you for 20 years of service to the government. So, thank you very much, Judy.

Judy Sparrow – Office of the National Coordinator – Executive Director

Thank you Paul, I've enjoyed every moment. Thank you.

Paul Egerman – Businessman/Entrepreneur

And it's amazing to me, I think you probably have enjoyed every moment, because probably the rest of us we would have had 1 or 2 moments that we probably would not have enjoyed, but Judy.

Judy Sparrow – Office of the National Coordinator – Executive Director

I wasn't laughing, really.

Paul Egerman – Businessman/Entrepreneur

But, Judy, really did. So today's topic relates to what we're calling the research recommendations related to the ANPRM and to try to explain the goals of what we want to do today and to frame our discussion, basically that's what we are going to be doing. In a few minutes Deven is going to be framing the first of 2 questions that we have to discuss. And what we're going to be doing is framing it in the context of the core values that this Tiger Team has already established and has been approved by the Policy Committee and we're also going to be framing it in terms of reviewing the previous recommendations that have been approved by the Policy Committee related to Fair Information Practices and also related to this issue of consent.

And so we're going to do that as a basic review and then what we hope to do is have a discussion this afternoon or this morning to talk about what we are calling the draft recommendations for the ANPRM and you see written on the bottom of your screen in really small font that we need to achieve consensus prior to the Policy Committee meeting on September 14th, which is Wednesday, which means we hope to get consensus as much as we can in this meeting. We will not probably try to get consensus on the final wording of a document, but to try to see if we can get consensus on some basic concepts.

And, also in terms of making sure that we understand the discussion that the ANPRM really focuses on the Common Rule and not HIPPA and the second bullet is really important, that we have this time constraint that I just mentioned and as a result we ourselves are not going to weigh in on all the issues in the ANPRM. These are fascinating issues but we are really going to try to be very, very focused, and so we're focusing on the things that are discussed in the 3rd bullet, which is sort of like the use of data from EHRs that's initially garnered for treatment but then it is secondarily used for other purposes like evaluations, assessments, reports, quality initiatives, that's what we are going to be focusing in on most of our call today to make sure that there is clarity on those issues as it relates to the ANPRM and the Common Rule, and as I said before we are doing this in a way that we hope to build upon previous Tiger Team recommendations.

And there are really 2 questions that we hope to address today and on the next slide Deven will take us through the first question and also Deven, hopefully I, do you have anything to add to what I just said?

Deven McGraw – Center for Democracy & Technology – Director

No, no, no. I think, I think you framed it quite nicely. I've had a little bit of trouble pulling up the slides but I'm getting them up now. So we should be on.

Paul Egerman – Businessman/Entrepreneur

Yeah we're on number 4.

Deven McGraw – Center for Democracy & Technology – Director

On slide number 4, thank you very much. So, essentially what we had circulated to you more in advance of the slides was this sort of background document that we've been trying to work our way through and build on and that you all have really done a tremendous, tremendous job in giving us early feedback on. I'm certain that we wouldn't be as far down the road as I think we are if we had not had you all working hard off line, in between calls, reacting to materials that we sent you, and I sort of feel like, you know, with each and every iteration this document gets more clear, more precise, more understandable, and potentially more worthy in contributing to the discussion about this really important set of issues.

And so, you know, what we did, as a result of some of your comments was to provide a lot more framing in the document so that it's a lot more clear about what it is we're actually aiming at with this set of

recommendations. And that is that, you know, number 1 with respect to question number 1, we're confining the recommendation to provider entities, in part because that's really the sort of set of entities that we are customarily called upon to make recommendations about their use of data, right. We acknowledge the fact and we acknowledge in the document that there are many other types of entities that are involved in the research enterprise including health plans. But, because we're trying very hard to use the Policy Committee's expertise to comment on things that the Policy Committee has some expertise on we really thought it was important to say these recommendations are meant to, you know, we are directing them towards provider entities because that's the set of entities that we customarily provide recommendations with respect to but we certainly invite you to apply them more broadly to other entities in the research enterprise if you find that appropriate.

Secondly, there seemed to be some confusion about whether or not IRB approval was at issue with respect to, again, secondary use of data and EHRs. As Paul said, we're, you know, confining the scope of what we're looking at to that particular set of circumstances and the fact is, is that there is an exemption already in the Common Rule from the requirement for IRB approval for research and the ANPRM retains that exception for secondary use of data that is collected initially for a treatment or non-research purpose, but what the ANPRM does do is require really a general consent when that data is used for research and is identifiable, and also requires some, is proposing to require some minimal registration with a one page document of those projects, which I didn't put on the slide, but we know from our previous discussions of the ANPRM that that is the case.

And then we continue to talk about the way that, you know, the technology is really enhancing the ability to assess healthcare quality, safety and effectiveness, and improve the way that providers effectively treat patients. We, you know, I think sometimes it is not always clear when something falls into a category of operations and when it falls more into a category of actual treatment and so we sort of broaden the aperture a little bit in this framing to acknowledge that what the technology does is really enhance our abilities both with respect to treating patients as well as evaluating how that treatment is performed retrospectively.

And then we continue to acknowledge that there is this goal of a learning healthcare system that it has been, you know, adopted wide spread by HHS including ONC and its programs. So, we go on to talk a little bit about the ways that, you know, clarifying what constitutes research could actually remove some real or perceived obstacles. Again, the document really acknowledges that the ANPRM is trying to already provide an easier pathway for secondary research using EHR data. So our recommendations are really saying okay you did some good things but you didn't quite do enough and in fact we're suggesting that you ought to really consider what really should be in the bucket of research at all, and that clarifying that definition could actually, potentially remove some obstacles and then we talk a little bit about how both in the Common Rule and also in HIPPA whether something is or isn't research is sort of pinned on whether a primary purpose is to contribute to generalizable knowledge. But, of course, in a learning healthcare system, right, we want to be contributing to generalizable knowledge ideally with the activities that we are doing here.

And, so those definitions, again could pose either real or perceived obstacles to the performance of those very activities that we want to really be encouraging. So, with that sort of more flushed out background that is now in the document, we move to what's in the draft recommendations, and here we took out some language that a lot of you had questions about, you know, are we just talking about routine care, you know, routine treatment activities, and just, you know, activities that we expect providers to do, that was some of the earlier language that we had in there, you know, instead we're really saying look if what we're talking about is using EHR data for treatment purposes or to evaluate the safety, quality and effectiveness of prevention and treatment activities, that really shouldn't be considered research and therefore shouldn't require either consent or IRB approval or registration.

And then we go onto say that this exemption should apply even if one of the purposes is to contribute to generalizable knowledge and to publish the results. Now, we have, I'm just going quickly through this initially and then we'll open the floor up to discussion that Paul is going to help manage. I'm just going to quickly draw your attention to some new language that we put in a new b, which you have not seen yet,

and that is to say that we wanted to more, after Paul and I had sent out the document we had a discussion with Rich Platt, who is a researcher as you know, and has been enormously helpful in helping us pull these recommendations together. We've had a number of discussions with him in addition to getting feedback from all of you, and one of the points that he made that we realized we did not think we made quite strongly enough, and maybe we haven't still made it strong enough in the language that I'm about to go over with you, but nevertheless, we wanted to strengthen the point that notwithstanding that IRB approval wouldn't be required and we're saying that consent shouldn't be required, even if it's identifiable data, we really expect these entities to maintain proper oversight over and be accountable for the conduct of these activities, and that is certainly consistent with our previous, with our core values, and our previous recommendations that really acknowledge that the provider entity is the locus of trust for patients with respect to data exchange and use, and that provider entities are responsible for the data uses that, you know, that are under their stewardship.

So, we continue with a point, and again I'll open it up, so I just want to quickly sort of set the scene here. We talk about how, you know, you shouldn't require consent even if the data does not qualify as either a limited data set or de-identified data, but of course, we would expect that a provider entity would always use the minimum necessary amount of data to accomplish these activities including removing identifiers when it's not necessary to identify individual patients, and this is certainly consistent with our previous recommendations on Fair Information Practices and any HIPPA entity that is subject to the minimum necessary rule which applies in all cases except treatment.

And then finally, we just put a few examples of the types of activities that we think would be covered by this recommendation, i.e., not considered to be research, and we wanted to make sure it's not an exclusive list, and it's very generally worded here, and we didn't want to get into too much detail, but just to give a flavor, but I hope you saw in the document that we circulated that we acknowledged that we had received from Judy Faulkner a number of examples from healthcare providers and researchers of the types of activities that they are concerned might be considered research in an environment where there isn't clarity about the rules and that they wanted to make sure got preserved and we would present those not as endorsed examples of the Tiger Team, because we don't actually have time to go through all of them, but just material that we had received from persons who were interested in our discussions and wanted to weigh in on what we were saying.

So, and we'll definitely share all of those with you, we haven't had a, my apologies, we should have gotten them out to those of you who don't have them, but again, we're not presenting them as Tiger Team endorsed examples, but rather, you know, here people weighed in on this and they're concerned about it and we thought that you might find their thoughts helpful as well.

And then the second piece of this, you know, goes into the issue of when the recommendation about research exemption would apply and here's where we get into issues about, you know, about provider entities maintaining control over decisions about how their data is used, but since we have a number of sort of corollaries to this second piece of our recommendations to question number 1, I'm going to stop because I've been talking for quite a long time without giving anybody a chance to interrupt or ask questions, and I'm going to, I think we should open this up now for questions, discussions, concerns, etcetera, and Paul I'm going ask for your help in helping us manage the discussion so we can get through it.

Paul Egerman – Businessman/Entrepreneur

Great, and thanks Deven, and great job in walking us through that and it is a complicated recommendation because, you know, the pieces are sort of like interwoven here, so there's a lot of pieces to it, and what I was going to suggest we do is that we go back through it and walk our way through it and people comment on it.

Deven McGraw – Center for Democracy & Technology – Director

Okay.

Paul Egerman – Businessman/Entrepreneur

Unless there are some, does anybody have a general comment they want to make first?

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

I do Paul. This is Dixie Baker.

Paul Egerman – Businessman/Entrepreneur

Okay.

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

It's not clear to me whether these are new ideas of whether we're agreeing with what's in the ANPRM or disagreeing, or so as we discuss them it would be useful to have that bit of information as well.

Deven McGraw – Center for Democracy & Technology – Director

You know, you know, Dixie, that's a really good question. I think you could argue that we are agreeing with the ANPRM in many respects because they are stating very clearly that this type of activity should not require IRB approval, but we are actually going a step further than where they went because we are suggesting that this type of activity shouldn't really be considered to be research at all and should instead be considered to be sort of part of arguably normal treatment and operations of a provider or provider entity, which means that, you know, then these activities would not be subject to the consent, even the general consent requirements that the ANPRM suggests would apply in the case of the use of identifiable data or data that at least doesn't meet the limited data set or de-identified data definitions. It might not be and ideally wouldn't be fully identifiable, but still it's considered to be identifiable per HIPPA definitions since the ANPRM goes in that direction and then we're also suggesting that the idea that the ANPRM promotes requiring registration of these activities also isn't necessary.

Paul Egerman – Businessman/Entrepreneur

So, in effect, Deven, let me see if I'm saying this right. We're really doing 2 things. Where one is this, we're just getting clarity about these activities as it relates to ANPRM and the second thing is we're also sort of harmonizing the consent aspects with the other consent recommendations we've made.

Deven McGraw – Center for Democracy & Technology – Director

I never know what people mean when they say harmonize.

Paul Egerman – Businessman/Entrepreneur

I know, I don't either, but it looks good.

Deven McGraw – Center for Democracy & Technology – Director

No, I think we're doing more than that.

Paul Egerman – Businessman/Entrepreneur

Okay.

Deven McGraw – Center for Democracy & Technology – Director

I think we're actually saying, because the Common Rule governs research and the ANPRM then therefore governs research. The ANPRM is taking the pathway of saying we're still going to consider this to be research but we're going to loosen up some of the requirements on it, but we're still going to have, we're still going to call it research and we're still going to require it to be registered with an IRB even if approval isn't required and when data is being used that is in a limited data set or de-identified data we're going to require you to get a general consent from patients to use their data for this purpose.

And so, the big difference that we're saying is that you know what there is a class of activities that should be so normal to operations in a learning healthcare system that they shouldn't be considered to be research at all and they just should be regulated in the way that we regulate entities doing these types of activities today when they are considered to be operations, which is to say you're accountable for them, you need to use minimum necessary, you have to protect it from a Security Rule stand-point, but these

above and beyond requirements that might attach in a research context, even if they're minimal, we don't think they're necessary, and we think they could be obstacles, that's I think what we're saying.

David McCallie, Jr. – Cerner Corporation – Vice President of Medical Informatics

So are we open for questions? Comments?

Paul Egerman – Businessman/Entrepreneur

Yes. We are David.

David McCallie, Jr. – Cerner Corporation – Vice President of Medical Informatics

So, this is David, first off I really like this. I think it's really well written, it's very clear and it feels right. So, my question is really designed to help kind of illuminate the boundaries of what is or what isn't inside our scope of the, I don't want to use the word exemptions, but the stuff that we should consider to be essentially part of healthcare operations.

Deven McGraw – Center for Democracy & Technology – Director

Right.

David McCallie, Jr. – Cerner Corporation – Vice President of Medical Informatics

So, there is no mention of the words "retrospective or prospective" and they may not belong in here, but I'm wondering if that is in some sense one of a key differentiators between what is truly research, which would be things that are prospective where you generate a, you have a hypothesis that you intend to test and you gather new data versus retrospective, which is stuff essentially that is already in the EHR as a side-effect of care having been delivered. Is that a decision that fits what we're trying to do?

Paul Egerman – Businessman/Entrepreneur

Well this is Paul. It's a good question. I was a little bit, originally I thought that that would be, you know, similarly thought that retrospective was a good approach, however, as I thought some more about this it also occurs to me like technology is changing and I'm not sure retrospective is the right word for the way some of these quality conditions are occurring.

Deven McGraw – Center for Democracy & Technology – Director

Can somebody who's in a public place please mute.

Paul Egerman – Businessman/Entrepreneur

Yeah, sometimes these things happen like in real time.

Deven McGraw – Center for Democracy & Technology – Director

Yeah.

Paul Egerman – Businessman/Entrepreneur

It's also the case that sometimes people do these things I think to test the theory in other words you read a study that says, you know, if you elevate the patient's bed 7 degrees then you'll have a reduced incidence of a certain type of pneumonia, so you say hey let's see if we can do that and see if we get the same result, and you know, that would be a perfectly reasonable thing for, in my opinion, for a hospital to do and so they are testing the theory to see if it can give them a positive result so.

David McCallie, Jr. – Cerner Corporation – Vice President of Medical Informatics

If you're doing a new intervention that potentially affects the patient wouldn't that require an IRB just from the point-of-view of the potential implication of a randomized treatment?

Deven McGraw – Center for Democracy & Technology – Director

Well only if you're randomizing, David, I think.

David McCallie, Jr. – Cerner Corporation – Vice President of Medical Informatics

Well prospective trials are always randomized.

Judy Faulkner – EPIC Systems Corporation

Well that why it's a little, this is Judy, that's why it's a little tricky I think.

David McCallie, Jr. – Cerner Corporation – Vice President of Medical Informatics

Do you not always randomize?

Judy Faulkner – EPIC Systems Corporation

I was just thinking of the young woman who showed, it was a girl not a woman, child who showed up with rabies, you don't see that often, she will die because everybody dies and so they try something different with her and that's prospective. And then others who had the same, this supporting Paul's example, others who have a rabies accident victim show up in front of them tried exactly what that person tried, so it's a very real example.

David McCallie, Jr. – Cerner Corporation – Vice President of Medical Informatics

Yeah.

Paul Egerman – Businessman/Entrepreneur

Yeah and the example. Thank you, Judy. The example I gave was actually a real example that happened where a research study actually occurred someplace else and there were results and so now the question is, you know, can we give this a try and reproduce it. I think that some of that is just the real world it's how these things are implemented.

John Houston – University of Pittsburgh Medical Center – NCVHS

This is John Houston. And to follow up on David's comment, I think there is a point where you have either a, maybe the key here is to use the word unapproved treatment activity, because there are a certain class of activities that are clearly within the domain of research and so when we look at like slide 6 where you talk about evaluating the safety, quality and effectiveness, maybe what you need to do is say of approved prevention and/or treatment activities, or make, try to move that outside the domain of what in mind is clearly research.

Paul Egerman – Businessman/Entrepreneur

Well John, this is Paul, that's a good comment. We actually tried that in an earlier wording. The wording that you see here, the way we approached it, was based upon the feedback we got from everybody. So, we tried like 2 or 3 different words. We tried to do like, use the word like routine or we tried to use the word like.

Judy Faulkner – EPIC Systems Corporation

Paul.

Deven McGraw – Center for Democracy & Technology – Director

Expected.

Paul Egerman – Businessman/Entrepreneur

Expected providers and people objected to that and so we.

Deven McGraw – Center for Democracy & Technology – Director

...

Paul Egerman – Businessman/Entrepreneur

What we settled on instead was this statement plus the statement later on this is where you have to have oversight of what's going on.

Deven McGraw – Center for Democracy & Technology – Director

Right, that.

Paul Egerman – Businessman/Entrepreneur

That was the formula, now that's not, what I just said was like the history of how we got to this point, that's not to say that's what everyone wants to do. We could.

John Houston – University of Pittsburgh Medical Center – NCVHS

Right.

Paul Egerman – Businessman/Entrepreneur

You know.

John Houston – University of Pittsburgh Medical Center – NCVHS

I just think we want to be, there are certain things that are clearly within the domain of the IRB.

Deven McGraw – Center for Democracy & Technology – Director

Yeah.

John Houston – University of Pittsburgh Medical Center – NCVHS

And I just, I think when we talk about, you know, approved or you know, there is some, I believe approved is something that you know, is used often in IRB parlance but we should figure out what that word is and try to use it or to qualify our comments.

Paul Egerman – Businessman/Entrepreneur

Yeah.

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

I agree with John, I think that is a good improvement here and I don't agree that retrospective versus prospective has much to do with it at all because there are some really solid retrospective studies that certainly advance our knowledge in medicine.

David McCallie, Jr. – Cerner Corporation – Vice President of Medical Informatics

No, I was arguing that retrospective is automatically included in what we're talking about here, Dixie, I mean I'm saying retrospective is a no-brainer, that's covered, the question for me is, is would a prospective intervention be covered even if it was, when would that be exempted somehow from being considered research. So, you know, for example let's say we wanted to do an experiment on a new way of delivering a decision support alert and we're going to randomize so that half the patients get the old alert and the half the patients get the new alert, and we want to look, you know, watch the EMR develop over the course of a year and see if there's a difference in outcome, in other words is the alert effectiveness changed? Is that research or not, it's entirely.

Deven McGraw – Center for Democracy & Technology – Director

Well yeah.

David McCallie, Jr. – Cerner Corporation – Vice President of Medical Informatics

...in EHR but I would say today that's research.

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

I don't think that's.

Paul Egerman – Businessman/Entrepreneur

Yeah, as I understand your, hold off a second, if I can understand your example correctly though what is on the screen we would say, what you just described would not require like an IRB approval or registration?

Judy Faulkner – EPIC Systems Corporation

And this is Judy. I think it's, I've seen some users of EHR software do similar things to that because of fatigue alert they experiment on where do you get the best results with people using the system and they

found that if they have too many alerts they were not getting good results and how do you ramp it down so you get people paying attention to the really important ones and you get rid of the unimportant and if you have to apply for IRB for all of that, that's a little weird.

David McCallie, Jr. – Cerner Corporation – Vice President of Medical Informatics

Well, but Judy.

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

And Judy has come up.

David McCallie, Jr. – Cerner Corporation – Vice President of Medical Informatics

If you look at David Bates work, you know, where many of these fundamental decisions about how to deliver decision support where hashed out those were all IRB based, because they were experimenting on the outcome and effect on patient health was not known.

Deven McGraw – Center for Democracy & Technology – Director

So let me make a suggestion here.

David McCallie, Jr. – Cerner Corporation – Vice President of Medical Informatics

I'm not saying these should be, but I'm just saying.

Judy Faulkner – EPIC Systems Corporation

Yeah.

David McCallie, Jr. – Cerner Corporation – Vice President of Medical Informatics

They weren't.

Judy Faulkner – EPIC Systems Corporation

I just think it's weird because I think a lot of users of the software do try to figure out because even putting in the system to begin with is new. So then, if you want to take what you're saying further on then they would need an IRB for setting it up in the first place.

Deven McGraw – Center for Democracy & Technology – Director

Right. So let me. Can I suggest something here?

Neil Calman – The Institute for Family Health – President and Cofounder

Can I make a comment, this is Neil?

Deven McGraw – Center for Democracy & Technology – Director

Yes and then I really do want to suggest something because I think there is a way to resolve this and I want to.

Neil Calman – The Institute for Family Health – President and Cofounder

I do too.

Deven McGraw – Center for Democracy & Technology – Director

Suggest it, but go ahead Neil.

Neil Calman – The Institute for Family Health – President and Cofounder

I don't think it has any, I think we're talking; I don't think whether it's IRB approval or not is really the question. You know, the IRB can approve things, you know, our IRB can approve things administratively, they can review something and declare it exempt. I mean these are institutional policies and there are things that we bring to IRB when we're working with NYU that NYU doesn't think needs to go to their IRB and visa versa. This is not like a hard and fast kind of a situation. This involves an assessment of risk. So, if you're doing something where there's a potential for risk then, you know, whether or not it falls into a prospective, you know, prospective category one way or the other you might determine it goes to an

IRB. But, if there's not really a prospective of risk you can bring it to your IRB and they can basically say, you know, that there's no reason to review it.

So, I don't really think whether it goes to the IRB or not is really the question. I think the question is really, and here is my suggestion, I think that there are so many variables involved in the way we're writing this letter that when you go to test it against real life cases that it's very hard to sort of figure out what is and what isn't within there. So, the first variable is whose doing it? Is it being done by the people who are entering the data, you know, the providers who are actually using it. Is it being done by somebody within that organization or is the inquiry being done by somebody who is a business associate, or is it being done by an outside 3rd party entity research group? And then you have the issue of what the activity is that's being looked at. Is it a, is it just a change in the way an alert is being sent or is it in a clinical protocol?

I mean, there are, I listed like 9 different variables and I think it would be helpful for us to sort of think of this in a matrix and be able to sort of chart this out at the end to say what are the triggers that either include or exclude this from, you know, from whatever that broad category is that we think needs to be reviewed.

Deven McGraw – Center for Democracy & Technology – Director

Okay so.

Paul Egerman – Businessman/Entrepreneur

Deven you want to make an observation?

Deven McGraw – Center for Democracy & Technology – Director

So, which is actually somewhat similar to what Neil suggested, although not the matrix, because quite frankly I don't think we have enough time to do the matrix. But, I do think, I did like what I heard in Neil's point is that institutions, provider entities are the ones who are accountable for things that go on with data that is generated from their records and the fact is, is that what we say about what ought to be required under the ANPRM it certainly does not take away the judgment call that an institution can make in managing the activities that take place using the data for which it has stewardship responsibility to place review on things, to, you know, even if it's not required. If they want to not ever be reviewed on something particularly in a circumstance where you are prospectively studying something to the point where you are randomizing people to 1 group or another, you know, that to me feels very different than, you know, several other circumstances that we could come up with. I'm suggesting that we acknowledge that part of the problem here is the drawing of the lines.

David McCallie, Jr. – Cerner Corporation – Vice President of Medical Informatics

Yeah.

Deven McGraw – Center for Democracy & Technology – Director

And even in trying to remove them and in testing where those parameters are we are having trouble.

Paul Egerman – Businessman/Entrepreneur

Right.

Deven McGraw – Center for Democracy & Technology – Director

With that and so that's why I'm suggesting that we sort of present this, we could add some language that acknowledges the line drawing difficulty and that the line drawing difficulty is part of the problem, and that certainly they, you know, we wouldn't want to be the final word on this and they could even gather more comments on where the lines ought to be, but at the end of the day, the entities are responsible for overseeing, and should be accountable for the conduct of anything that happens with data that they have stewardship over, which always gives them the ability to institute policies that protect them from liability, and that they feel are necessary in order for them to be accountable to their patients, and to the public, you know, with that kind of language, because we could literally spend the rest of this phone call arguing about whether an example is or is an out.

David McCallie, Jr. – Cerner Corporation – Vice President of Medical Informatics

Exactly.

Paul Egerman – Businessman/Entrepreneur

But, Deven, it's what you're. I don't understand this, how is what you just said different than what is in red on the screen right now?

Deven McGraw – Center for Democracy & Technology – Director

I, you know, it doesn't, I don't think it's different other than to say that we acknowledge that the category of activities that we think are exempt from research, that, you know, there are still likely going to be questions that will arise for any one particular activity as to whether it sort of falls in the bucket of likely to be exempt or whether it ought to be, you know, sort of subject to some additional requirements and, but what we're saying is that those judgment calls ought to be made by the institutions and the entities and not necessarily through the setting of rules and drawing of lines that end up creating more obstacles.

Paul Egerman – Businessman/Entrepreneur

So another way of.

Deven McGraw – Center for Democracy & Technology – Director

It's just a more flushing out of b.

Paul Egerman – Businessman/Entrepreneur

So another way of doing that to pick up on Neil's comments would be to expand what section b says that's in red where it says, you know, entities need to maintain proper oversight and to be accountable for the conduct of these activities, then say something like and to ensure that these activities do not increase the risk to the patient and probably using different wording or.

Neil Calman – The Institute for Family Health – President and Cofounder

Paul, I was going to suggest that basically it says that this, that ultimately the decision based upon a professional assessment of potential risks. That's basically, that's really what we're saying. We're saying that there are no hard and fast rules; somebody is going to have to, as we do now, for everything that we do, depend upon an assessment of risk.

Deven McGraw – Center for Democracy & Technology – Director

Yep.

Paul Egerman – Businessman/Entrepreneur

Well.

David McCallie, Jr. – Cerner Corporation – Vice President of Medical Informatics

That's what we have IRBs for.

Paul Egerman – Businessman/Entrepreneur

This is where.

Neil Calman – The Institute for Family Health – President and Cofounder

That's what we do.

Wes Rishel – Gartner, Incorporated

This is Wes. At this point I'm not sure that we have anything to say. If I recall the history of this item, and I could be wrong, we were concerned about a phenomenon that we often hear about from Judy, which is that in practice, in settings, you know, in provider entities, regulatory language generates a spectrum of interpretations and the worst case interpreters tend to create a lot of obstacles when compared to medium middle range interpreters, and we were hoping to create some, take out at least some situations and provide some clarity so that, about the issue of whether this is research and therefore regulated by

the Common Rule, or whether this is not research and therefore regulated by HIPPA. At this point, you know, I don't think we have anything to say. I would just say that just deleting the whole thing would be the most parsimonious expression of what we've done.

Deven McGraw – Center for Democracy & Technology – Director

Well thanks, Wes,

Paul Eggerman – Businessman/Entrepreneur

Wes, when you say delete it are you talking about just section b or the entire recommendation?

Wes Rishel – Gartner, Incorporated

I don't know.

Paul Eggerman – Businessman/Entrepreneur

I was trying to understand what you just said.

Wes Rishel – Gartner, Incorporated

Well, I'm, the statement we've got now is.

Deven McGraw – Center for Democracy & Technology – Director

Wes, can I ask when you joined the call?

Wes Rishel – Gartner, Incorporated

Almost at the start. I think I was about maybe 8 minutes.

Deven McGraw – Center for Democracy & Technology – Director

Okay.

Wes Rishel – Gartner, Incorporated

Or 7 minutes into the call or something.

Deven McGraw – Center for Democracy & Technology – Director

Thanks. Okay. Because to me, I do think that we are saying something different from the direction that the ANPRM is making. It's not something that probably doesn't require some further thought on the part of HHS. I mean keep in mind this is an ANPRM, an Advanced Notice of Proposed Rule Making, chance to weigh in on the early side, I don't think we have to have all the answers to all the questions, but I do think that in fact, first of all HIPPA also regulates research, whether it's Common Rule or whether it's HIPPA depends on whether it's federally funded, and whether the entity doing the activity is a covered entity or not a covered entity.

Second of all, you know, the issue of whether the activity that you're conducting is contributing to generalizable knowledge and having that be the primary trigger in considering whether it's research and therefore there should be greater obligations on it then operations, for which there are fewer obligations on it, there are none if your just Common Rule regulated, there are HIPPA ones if you're a HIPPA person, but it's a different regulatory scheme for certain and the fact that we want to create a learning healthcare system where we're encouraging more people to publicize the results of some of the internal quality assurance activities that they do so that we can all learn from them, that alone is, you know, is creating an obstacle and we're saying don't define it this way.

You know, whether that means we should be saying, whether we need to frame it as not about whether it's research or not, but whether there's a category of activities that ought to be able to go forward even without necessarily requiring patient consent, I mean, we could, we could talk about that, but I do think that.

Wes Rishel – Gartner, Incorporated

Well, maybe I'm, I'm just trying to get to my copy of the deck so I can see a of this draft recommendation, but, what I'm hearing is now where back farther than a.

Paul Egerman – Businessman/Entrepreneur

Oh sorry, is that where you want to be.

Wes Rishel – Gartner, Incorporated

Now we're back to where we were again.

Paul Egerman – Businessman/Entrepreneur

We've got 2 pilots here.

Deven McGraw – Center for Democracy & Technology – Director

Go ahead Paul.

Paul Egerman – Businessman/Entrepreneur

I got it. Okay.

Wes Rishel – Gartner, Incorporated

Okay.

Paul Egerman – Businessman/Entrepreneur

Explains a lot of things that we couldn't get on the right slide.

Wes Rishel – Gartner, Incorporated

All right.

Wes Rishel – Gartner, Incorporated

Okay so 1 stands, right. We're not discussing 1. We're not discussing.

Paul Egerman – Businessman/Entrepreneur

Right now, well, right now here's what we're discussing, the way I understand this discussion, this is a good question, is we've got this wording in section 1 that says that, you know, when you use the EHR data to evaluate safety, quality and effectiveness that's like a carve out, it does not require consent or IRB approval or registration, and then, and we're saying that exemption would apply even if the results are intended to or end up being publicized. And what I've heard is, I haven't heard disagreement with that, I've heard concern about what is in red here, in other words, well how do you know it's not like a completely different treatment and how do you know there's not risk, and what I've also heard is like 3 different responses to that or maybe there's 4, but we have what we already have in red, which is provider entities need to provide proper oversight. Then John Houston made a comment that it needs to be somehow like regular medical standards of treatment. Neil Calman said it really needs to be, as an alternate approach, he said you know it really involves a professional assessment of risk whether or not your adding additional risks to the patient, and then Deven suggest well maybe the thing to do is simply say, acknowledge that it's a fine line and you can't necessarily define it.

Wes Rishel – Gartner, Incorporated

Well, why.

Paul Egerman – Businessman/Entrepreneur

And we can acknowledge that. Those are, I don't think.

Wes Rishel – Gartner, Incorporated

Yeah, okay. So, I appreciate the recapitulation it's helpful. I was reacting really to Neil and to Deven, and there's two ways of interpreting that. I was interpreting Neil as saying we need to add more to this about how risk is evaluated in order to make the case that we're making here. I was hearing Deven say we can't be as specific as we are now trying to be, therefore, we should make some general statement, and

my sense is that if it's any more general than this it's, I mean, it would be nice to go on record as saying we think something ought to be done here, but it wasn't very satisfying at the conclusion. I just want to ask again what's wrong with the language as it's on the, I mean I don't want start the whole debate over again, but I think this is pretty clear.

Paul Egerman – Businessman/Entrepreneur

In other words your comment, where you say, particularly you say, are you saying you like what's on the screen?

Wes Rishel – Gartner, Incorporated

Given the framing that Deven just made, this is a comment to go to the Policy Workgroup to be a response to the ANPRM, which itself will be substantially reworked and there will be other opportunities to drill down on specifics, I think we carve out a clear position with this language and we frame a discussion about it. That's pretty good.

Paul Egerman – Businessman/Entrepreneur

Yeah, well, first of all I agree that it's pretty good. I think this group has made really excellent progress. What the discussion indicates is actually both an interesting and very challenging topic, and so I think it is pretty good, and if I'm hearing what you're suggesting, Wes, is you're saying you like what it is and we don't need to expand on.

Wes Rishel – Gartner, Incorporated

We need to rely on downstream processes to expand on it rather than feel like we are ourselves drafting a regulation here.

Paul Egerman – Businessman/Entrepreneur

Okay, so let me ask, John, Neil, and Deven what you think of Wes's suggestion.

Deven McGraw – Center for Democracy & Technology – Director

I think its fine.

Paul Egerman – Businessman/Entrepreneur

John?

John Houston – University of Pittsburgh Medical Center – NCVHS

I'm sorry I was on mute, sorry.

Paul Egerman – Businessman/Entrepreneur

Yes.

John Houston – University of Pittsburgh Medical Center – NCVHS

Just going back to slide 6 I just still think there is a difference between what I will characterize again as being sort of approved in those things that are clearly endeavors into the unknown and to the things that, you know, are clearly not within the realm of treatment, you know, and so adding something like the word approved simply make sure we frame it clearly and what realm what we're trying to work in.

Wes Rishel – Gartner, Incorporated

Well the problem I have with that is we're saying that certain kinds of approved things don't need IRB approval. I mean.

John Houston – University of Pittsburgh Medical Center – NCVHS

Approval by whom? I'm worried about the opposite where people don't feel like they have to get IRB approval for things that are so clearly new endeavors that they should.

Wes Rishel – Gartner, Incorporated

But the problem is approved, you know, saying that something is approved as a criterion for deciding whether it needs approval is circular.

Deven McGraw – Center for Democracy & Technology – Director

Yes.

Neil Calman – The Institute for Family Health – President and Cofounder

And 30% of all drugs that are prescribed are prescribed for off label uses, so I mean, we're not, to some extent none of those are approved uses.

Paul Egerman – Businessman/Entrepreneur

Yes. This is Paul. One of the things that happens between meetings is I had a phone call with Judy Faulkner and a physician who works for her whose name I forget, and Judy you have to tell me.

Judy Faulkner – EPIC Systems Corporation

Jessica.

Paul Egerman – Businessman/Entrepreneur

If I'm explaining this right, but I asked her a similar question and I may be getting this wrong, but she would say something like, you know, we live in this culture of physicians do no harm and so, you know, there's so much of this, there's do no harm, and I don't know if she said this but, you know, in such a litigious environment that there's already built into the environment a lot of protections against, doing really odd and crazy things.

John Houston – University of Pittsburgh Medical Center – NCVHS

Yeah, one of which is the IRB.

Deven McGraw – Center for Democracy & Technology – Director

Well, so here's what I, Neil are you okay with the language as is to Wes's comment?

Neil Calman – The Institute for Family Health – President and Cofounder

Yeah. My statement was really only that I think to acknowledge the fact that risk assessment is what this professional judgment is based upon.

Deven McGraw – Center for Democracy & Technology – Director

Yes.

Neil Calman – The Institute for Family Health – President and Cofounder

And I think that it helps to clarify this a little bit, but I mean, if people don't want to edit it at all I think, you know, I don't have any objection to what you wrote originally. I just think that helps to clarify it a little bit.

Deven McGraw – Center for Democracy & Technology – Director

Yeah. So, what I'm going to suggest is to John's concern that we specifically Tee that up for the Policy Committee as one issue upon which we didn't, you know, there were some members who still wanted to place some language that would attempt to confine or define the scope of what we're talking about in recommendation number 1, but that others, but number one we couldn't agree on what that language would be, and many others felt as though it really ought to be subjected sort of downstream policies and procedures that would be you know, developed by the provider entity based on its own evaluation and management of potential risks.

Paul Egerman – Businessman/Entrepreneur

That maybe, Deven, let's just spend a few more minutes on it though because maybe we can get to a.

Deven McGraw – Center for Democracy & Technology – Director

I don't like the word approved for the same reasons that Wes doesn't.

John Houston – University of Pittsburgh Medical Center – NCVHS

And I agree. I mean, this is John Houston. I agree with Deven's approach, I mean, because it really does Tee the issue up which is really.

Deven McGraw – Center for Democracy & Technology – Director

Yes.

John Houston – University of Pittsburgh Medical Center – NCVHS

The fundamental issue of boundary and it really isn't one word, we could talk about this all day long and I agree with Deven.

Deven McGraw – Center for Democracy & Technology – Director

Yes.

Paul Egerman – Businessman/Entrepreneur

So could you repeat what you want to do Deven?

Deven McGraw – Center for Democracy & Technology – Director

Yeah, so what I'd like to do is leave the language as is, but to specifically raise with the Policy Committee that in the presentation that we had a conversation about boundaries and whether in fact we had provided sufficient guidance around the exemption in number 1 or whether we needed to be more clear about the scope of that for fear that if we were opening that up too much that there would be activity that would happen that, you know, would arguably be research but we hadn't sort of come up with the right set of words to define the parameters very well and we've spent practically most of this call already on that very topic, and that we, you know, invite the Policy Committee to give us feedback on, you know, particularly on the issue of do we continue to try to find a way to confine it, do we just leave it up to the institutions to manage their own risks appropriately, do we specifically acknowledge that this was an issue upon which we debated but did not come to consensus on, just open it up for their feedback. I mean, they're ultimately the authority on what we are going to provide to HHS anyway if the Tiger Team is sort of honest about, you know, sort of where the touch points were, but that in, you know, basically we were in agreement on a number of key concepts. I think that'll still be, that still advances the ball.

Gayle Harrell – Consumer Representative/Florida – Florida State Legislator

This is Gayle. I would agree with you Deven with that and I think there will be further discussion, we ought to make sure that we allow enough time in the process.

Deven McGraw – Center for Democracy & Technology – Director

Yes, Gayle, we've asked for 75 minutes.

Gayle Harrell – Consumer Representative/Florida – Florida State Legislator

Okay, because sometimes those conversations get hurried and it doesn't really get hashed out like we can do in a committee.

Deven McGraw – Center for Democracy & Technology – Director

Yeah. Yeah. No I agree, although we've been hashing it out for probably at least two meetings now without as much clarity as we had hoped. It's a hard one. It's a hard one. I mean think about the regulatory drafters when they initially tried to draw those lines, and they said if it's contributing to generalizable knowledge then it's research, and if it's not then it's largely, then it's quality assurance and its internal and we don't have to worry about it, and that line doesn't work as well in the type of healthcare system that we want to see in the future where we are more of a learning healthcare system and we use data ubiquitously to improve healthcare at every opportunity. So, that's not a great line anymore, but it's really hard to figure out where the line ought to be drawn next.

Gayle Harrell – Consumer Representative/Florida – Florida State Legislator

Well, I think we need to say that very distinctly, to say that definition of research really needs a full scale conversation above and beyond us.

Deven McGraw – Center for Democracy & Technology – Director

Right, that's a good point. So is that, people, everyone comfortable with that? So, again the recommendation language would look like this but we would be adding some specific props to the Policy Committee to get their feedback and quite frankly if we land in exactly the same place the letter to HHS is going to acknowledge that.

Paul Egerman – Businessman/Entrepreneur

Yes and so the way I'm understanding what you're saying Deven, and picking up on what Wes said, is if we say that we've also made good progress, right, in other words it's an ANPRM.

Deven McGraw – Center for Democracy & Technology – Director

Yes.

Paul Egerman – Businessman/Entrepreneur

And we're saying this, these are the things we wanted to make sure there is clarity on, these are examples and besides the examples in this slide our plan would be to choose from the examples that Judy Faulkner and I think a few other people have, Rich Platt, have sent to us to make it clear and that that is, you know, it's an ANPRM, that's advancing things, we're explaining where we want clarity that IRB approval is not required and we're pointing out a place where there is a boundary challenge.

Deven McGraw – Center for Democracy & Technology – Director

Yes.

John Houston – University of Pittsburgh Medical Center – NCVHS

This is John Houston. I agree. I think it's incredibly important. I think in and of, this recommendation in and of itself really speaks strongly to what I think needs to be said.

Deven McGraw – Center for Democracy & Technology – Director

Right.

Paul Egerman – Businessman/Entrepreneur

Okay, so I just want to make sure.

Deven McGraw – Center for Democracy & Technology – Director

We're dancing Paul. I think we should move onto question 2.

Paul Egerman – Businessman/Entrepreneur

Okay.

Deven McGraw – Center for Democracy & Technology – Director

I mean not question 2, I mean sorry, draft the 2nd piece of the draft recommendations still applying to the research.

Paul Egerman – Businessman/Entrepreneur

Okay, let me just see, hold on a second. So just to make sure everyone's sees it there was a section c about whether or not qualifies the limited data set or de-identified data, so basically this says you can use identified data if you would like for these processes and then we have the examples, and the intent in the final letter will be to provide some more specific examples of, as specific as possible, of institutions who've done things to try to educate the agency that is receiving it. And then you want to go here, Deven?

Deven McGraw – Center for Democracy & Technology – Director

Yeah, that's right, but again, as I mentioned earlier those examples are not, we're not going to present them as Tiger Team endorsed examples, but examples of materials that people provided to us in weighing in with their thoughts on what we were considering.

Paul Egerman – Businessman/Entrepreneur

Yeah.

Deven McGraw – Center for Democracy & Technology – Director

Because otherwise we'd have to.

Paul Egerman – Businessman/Entrepreneur

That's right and the purpose for the examples is to try to illustrate the exact kinds of things that are going on right now and the kinds of things we want to make sure that there is clarity about.

Deven McGraw – Center for Democracy & Technology – Director

Yes.

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

This is Dixie, I don't understand Deven's comment that these are not Tiger Team examples.

Deven McGraw – Center for Democracy & Technology – Director

Well, because you all have, so here's the thing, we haven't seen them. I mean, I've seen them but I don't think everybody's seen them. We haven't vetted them with the Tiger Team. I don't think it's appropriate to say here's a set of examples that we read and that we agree should be included in the examples, but instead to acknowledge, you know, that people are extremely interested in what we, the direction we're going in and they have offered examples of activities that they think ought to be considered to be not research, and we think it's worthwhile for the HHS to see them.

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

But it does say in the text that I'm looking at the Tiger Team agrees should be covered.

Deven McGraw – Center for Democracy & Technology – Director

That's just the bullet; I'm sorry Dixie, that's just the bullet point. Paul, I have the slides.

Paul Egerman – Businessman/Entrepreneur

Pardon me?

Deven McGraw – Center for Democracy & Technology – Director

I just was telling you I have control of the slides, so I could go backwards to show Dixie that these examples in fact they're very nonspecific, they're very generally worded, those are intended to be presented as the types of activities that the Tiger Team thinks would be covered by this recommendation.

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

Okay.

Deven McGraw – Center for Democracy & Technology – Director

My apologies for not being clearer, I was referring to we have some text in the recommendations document.

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

Oh, I see.

Deven McGraw – Center for Democracy & Technology – Director

That basically we're going to attach some material that people gave to us that are much more specific. But, that I don't want to present as being endorsed by the Tiger Team because we, you know, we wouldn't have time to go through and vet them nor would it necessarily be I think important for us to do this. I think that you know, we are a committee that operates, you know, in the public and people submitted this material to us and I think we could submit it in that posture. Does that make sense?

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

Yes. Thank you. I appreciate it.

John Houston – University of Pittsburgh Medical Center – NCVHS

Deven, one comment about slide 8, these are all examples for one side of the recommendation or for the, in support of the recommendation. Should there be something that tries to clarify when something does require IRB, would require IRB approval, maybe I'm not saying it the right way, but.

Deven McGraw – Center for Democracy & Technology – Director

No, I know what you're saying, so we actually did have something in there on an earlier draft that said, you know, novel treatments or approaches would require IRB approval and people didn't like it, probably because it wasn't specific enough and we got ourselves right back, I think we'd get ourselves right back in the conundrum that we, of line drawing that we, without, you know, one specific use case of a novel treatment we might say yes that would require IRB approval, but I don't think we could blankedly say that there wouldn't be, that in all circumstances, you know, looking at something novel would always be research. So.

Neil Calman – The Institute for Family Health – President and Cofounder

Deven.

Deven McGraw – Center for Democracy & Technology – Director

I avoided it and for that reason it got us right back in the same conundrum we've been in.

Neil Calman – The Institute for Family Health – President and Cofounder

What I think what would be helpful though Deven, this is Neil, is some examples of the kinds of activities that would require individual discretion of the entities.

Deven McGraw – Center for Democracy & Technology – Director

But all of them would.

Neil Calman – The Institute for Family Health – President and Cofounder

Well.

Deven McGraw – Center for Democracy & Technology – Director

All of them would, Neil.

Neil Calman – The Institute for Family Health – President and Cofounder

But, we're saying that these don't. I mean then we should eliminate these.

Deven McGraw – Center for Democracy & Technology – Director

No, no, no, no that's not true. What we are saying is that activities that are exempt from research by the definition, in terms of being directly regulated by the Common Rule, would still be subject to oversight by the individual institutions in which they take place. All of these.

Neil Calman – The Institute for Family Health – President and Cofounder

Well everything is subject to.

Deven McGraw – Center for Democracy & Technology – Director

Well, that's exactly right.

Neil Calman – The Institute for Family Health – President and Cofounder

Right, so, but that's different than saying that there's a set of activities about which we're not commenting because they require the individual discretion, I guess it's different than just your sort of general oversight comment, basically you're saying you're still responsible for everything that takes place within the walls of your institution or with your data. Nobody would argue with that, but if you're going a step further and saying here's some examples of things that are covered by the recommendations we're making, then I

think, it does really, I mean in a sense it really does raise the question of so what isn't covered and what we're saying about the what isn't covered is where not going to say what isn't covered, what we're going to say is that things other than this require some review by the organizations in terms of determining whether or not they pose safety risks. Right?

Deven McGraw – Center for Democracy & Technology – Director

Does anybody else want to comment on that?

Neil Calman – The Institute for Family Health – President and Cofounder

In other words.

Deven McGraw – Center for Democracy & Technology – Director

I'm wondering. So are you suggesting that we remove the list?

Neil Calman – The Institute for Family Health – President and Cofounder

No, I'm saying there's only 2 categories, these clear things that we're calling out in this category, I'm saying that they're covered by the recommendation, and everything else that we're saying requires a risk assessment and the judgment of the organizations to determine what needs, you know, what types of review are needed.

Paul Egerman – Businessman/Entrepreneur

So I'm trying to understand Neil, is it your point that if we list it as an example the organization doesn't have to have oversight over it?

Neil Calman – The Institute for Family Health – President and Cofounder

No not that it doesn't have to have oversight over it, but we're saying these are, I guess maybe it's by this recommendation, is that referred back to the red clause that basically says everything is covered, I mean everything needs to, you know, is subject to oversight by the organization. Do you understand what I'm saying, like why are we calling out these individual items.

Paul Egerman – Businessman/Entrepreneur

I think the reason for doing it was simply to be illustrative, in other words to illustrate what we're talking about, the kinds of things that we're talking about.

Neil Calman – The Institute for Family Health – President and Cofounder

And what's the saying of the other things, I guess that's the question.

Deven McGraw – Center for Democracy & Technology – Director

Well, we weren't saying anything about the other things.

Paul Egerman – Businessman/Entrepreneur

Yeah.

Neil Calman – The Institute for Family Health – President and Cofounder

But that's my.

Paul Egerman – Businessman/Entrepreneur

You look at the last one, outreach efforts, you know, I mean maybe what needs to happen is if this is causing problems maybe we just say, but what we really want to do is be more specific in these kinds of examples and so that we would, you know, point out in the attachment maybe we don't necessarily include this in the body of the letter, which is part of the attachment, where there would be some of these examples if that's causing some confusion, but we, you know, you look at outreach efforts we're just simply trying to say, you know, if you want to send letters to patients to remind them to have mammograms that's, you know, that's reasonable.

Neil Calman – The Institute for Family Health – President and Cofounder

But those.

Paul Egerman – Businessman/Entrepreneur

And if you want to try to do something interesting or if you wanted to call people on the phone and remind them of their dietary restrictions.

Neil Calman – The Institute for Family Health – President and Cofounder

But.

Paul Egerman – Businessman/Entrepreneur

Since the phone calls improve compliance, that would also be something that we'd say that would not require IRB approval.

Neil Calman – The Institute for Family Health – President and Cofounder

But these things were never in question is my point.

Judy Faulkner – EPIC Systems Corporation

Oh, I think, this is Judy; I think they were Neil by some of the other stuff.

Neil Calman – The Institute for Family Health – President and Cofounder

Really?

Judy Faulkner – EPIC Systems Corporation

That was written earlier. Yeah, I think that the list is a really good list because things were in question and I do agree with you that b we expect provider entities to maintain proper oversight refers to everything.

Neil Calman – The Institute for Family Health – President and Cofounder

Right.

Judy Faulkner – EPIC Systems Corporation

And that given this list, which I think is a helpful list, and the comment that the organization has to have oversight over everything that the two together are good.

David McCallie, Jr. – Cerner Corporation – Vice President of Medical Informatics

So this is David. One of the concerns I have is what is the definition of proper oversight that's not IRB, are we envisioning something that's a lighter weight oversight than an IRB? Are we.

Deven McGraw – Center for Democracy & Technology – Director

Oh no, no, no. So we are not describing in any detail or dictating to an organization how it oversees the activities that, for which they are legally responsible, right. We're not going to say that if you wanted to use an IRB to do this you could, you know, the role that IRBs are required to play under the Common Rule is not aimed at, necessarily at minimizing institutional risk, and protecting, you know, and thinking about the institutions role within its community, but instead to weigh the risks to human subjects involved in the research and at times to weigh whether the potential benefit of that research outweighs those risks, it's a slightly different calculus, nevertheless, if an institution wanted to use its IRB for that purpose we're not suggesting that it couldn't we're just saying it's on you provider entity.

David McCallie, Jr. – Cerner Corporation – Vice President of Medical Informatics

But Deven.

Deven McGraw – Center for Democracy & Technology – Director

To oversee these activities as you do with anything that happens that is within the purview of your responsibility, but we're not going to tell you how to do it.

David McCallie, Jr. – Cerner Corporation – Vice President of Medical Informatics

Agreed, but this would, you know, back to Wes's controversial point a while ago, this is kind of a meaningless statement unless there is in fact something being carved out by what we're saying here of what is, we all agree on heavy weight process. We're saying there is some kind of a carve out, you still have to do oversight but it doesn't have to be full IRB oversight.

Wes Rishel – Gartner, Incorporated

No, I don't, I think we're simply acknowledging that everybody has this responsibility and we're not recommending that they be relieved of that responsibility it's a lot of times you put that stuff in just to avoid people from taking your recommendation farther than you intended it. And so I think its good as it stands.

David McCallie, Jr. – Cerner Corporation – Vice President of Medical Informatics

But we are carving them out for something.

Wes Rishel – Gartner, Incorporated

We're carving them out saying they're not.

Deven McGraw – Center for Democracy & Technology – Director

They're not research.

Wes Rishel – Gartner, Incorporated

Research. But that doesn't mean just because they're not research doesn't mean you don't have all the same responsibilities you have with the data you do with patient care.

Deven McGraw – Center for Democracy & Technology – Director

Right. But when they're not research they're not subject to the Common Rule at all.

David McCallie, Jr. – Cerner Corporation – Vice President of Medical Informatics

Okay, so we're carving them out from coverage of the Common Rule.

Deven McGraw – Center for Democracy & Technology – Director

Yes.

Paul Egerman – Businessman/Entrepreneur

That's right. But we're also not.

Gayle Harrell – Consumer Representative/Florida – Florida State Legislator

One more point, you could. This is Gayle. I think one of the reasons you do want to make a statement and these are very good examples as far as I'm concerned, is that you have the opportunity for bureaucrats and for assertive lawyers within an entity to, if you don't do kind of an explanation of what you're meaning, to really impose further restrictions and rules on the entity from within or from without. So that the explanation of kind of what the examples we're giving at least gives them an idea of what our thinking was.

Paul Egerman – Businessman/Entrepreneur

That's right and to be clear Gayle that's exactly what we're trying to do is we're trying to explain what our thinking is. It's a good summary of what we're trying to do with these examples and hopefully the more detailed examples that we will put as attachments to illustrate sort of where we're coming from.

Wes Rishel – Gartner, Incorporated

And as you guys present it we need to do some chest pumping because this is really an important thing that we picked up.

Deven McGraw – Center for Democracy & Technology – Director

Yes.

Wes Rishel – Gartner, Incorporated

Fished up out of the group here. So, so.

Paul Egerman – Businessman/Entrepreneur

You may need to give us some guidance as to how to best do that.

Wes Rishel – Gartner, Incorporated

Chest pumping? Well I'll be in the rooting gallery, oh no I won't this is.

Paul Egerman – Businessman/Entrepreneur

This is the Policy Committee.

Wes Rishel – Gartner, Incorporated

Policy Committee. Oh well.

Paul Egerman – Businessman/Entrepreneur

Well you can call in.

Wes Rishel – Gartner, Incorporated

I can make a public comment afterwards.

Paul Egerman – Businessman/Entrepreneur

So the purpose of these examples was simply to be, like Gayle's explanation, to illustrate our thinking. It was not to make anything specific, say anything specific about these or to change responsibilities for oversight. So are we okay with these? The examples? So let's move onto the next one.

Judy Faulkner – EPIC Systems Corporation

Before you go to the next can we go back one.

Paul Egerman – Businessman/Entrepreneur

Yes.

Judy Faulkner – EPIC Systems Corporation

Which was 1c.

Paul Egerman – Businessman/Entrepreneur

Back one more?

Judy Faulkner – EPIC Systems Corporation

Yeah, right there. I am confused about what that means because what I don't understand about removing patient identifiers, is does that mean that the provider is not allowed to utilize a data set that that contains.

Deven McGraw – Center for Democracy & Technology – Director

No.

Judy Faulkner – EPIC Systems Corporation

Other priors or just means.

Paul Egerman – Businessman/Entrepreneur

Just the opposite here.

Judy Faulkner – EPIC Systems Corporation

Okay. Can you maybe clarify that a little bit more because I couldn't figure out where the removing was, whether removing was before the provider researched that?

Paul Egerman – Businessman/Entrepreneur

Maybe it's because I saw a double negative here, consent is not required if the data does not qualify, maybe we need to write a little bit.

Judy Faulkner – EPIC Systems Corporation

Yeah, because otherwise the implication that you could possibly read into it is that everybody needs 2 data sets.

Paul Egerman – Businessman/Entrepreneur

No, so, I mean, yeah what I hear is maybe you're working on I don't know reducing re-admission rates and you need to look at some specific information about some specific patients.

Deven McGraw – Center for Democracy & Technology – Director

Yeah. No. I mean absolutely what was.

Paul Egerman – Businessman/Entrepreneur

You should be able to do that.

Deven McGraw – Center for Democracy & Technology – Director

Intended here Judy was when what you are doing doesn't need an identifier attached to the data we would expect to not, to, you know, to use identifiable data, but when you need it or you're incidentally exposed to it in the process of gathering your data set, I mean, you know, we're just trying to apply fair information practices.

Judy Faulkner – EPIC Systems Corporation

Okay and I get what you say. I still think as you said it, it could be construed as ambiguous.

Deven McGraw – Center for Democracy & Technology – Director

Okay, I'll work on it.

Judy Faulkner – EPIC Systems Corporation

And then, yeah. I think we have to make it clear that they don't need 2 data sets. It's how they get the data out and what they look at or print rather than what the data set is internally.

Deven McGraw – Center for Democracy & Technology – Director

Right. Yes.

Judy Faulkner – EPIC Systems Corporation

Okay, if you could make that clear.

Deven McGraw – Center for Democracy & Technology – Director

Yep.

Judy Faulkner – EPIC Systems Corporation

Thank you.

Paul Egerman – Businessman/Entrepreneur

Okay. So, we're going to move on to this section here. This says, consistent with the Tiger Team's previous recommendations the exemption only applies when the provider entity or OHCA retains oversight and control over, a lot of words, over their data.

Deven McGraw – Center for Democracy & Technology – Director

Well, no, but that's, those words are important Paul.

Paul Egerman – Businessman/Entrepreneur

Yes.

Deven McGraw – Center for Democracy & Technology – Director

Retains oversight and control about decisions regarding when their identifiable EHR data is used for quality, safety and effectiveness evaluations. And the reason why it's important to focus very specifically on that language is that we're not talking about loss of physical control of the data per se, but the idea, which we've initially advanced in our initial consent recommendations that patients trust their providers to protect data and as long as the provider retains control about how the data over which they have stewardship is to be accessed, used, and disclosed then, you know, then the consent requirement wouldn't be triggered, and so we're basically saying here that this, that recommendation number 1, which broadens the sort of activities that could be done that wouldn't be considered to be research really ought to be confined to circumstances where the entities, again, since they retain that responsibility and oversight and control over their data.

And so we got, you know, again in 2a, we've acknowledged the root of this recommendation that it emanates from some very good work that we did back just over a year ago, but it's not, you know, we wanted to make sure and we had this discussion in our previous Tiger Team that we weren't talking about needing to just keep the data internally you could still share data with others in a collaborative effort for quality, safety and effectiveness assessments, as long as, again, you're in control of your data and you're not just dumping it and providing it off to another entity that then has control over the data and makes decisions and you've lost your control over that data. So that's the sort of distinction that we're talking about and then, you know, we've sort of got the fair, you know, we've thrown in some Fair Information Practices with respect to, you know, how that data gets treated consistent with what we said in the first part of the recommendation.

So that's, I think you have to read it as a whole to understand it and to sort of see that it emanates not from the idea of you know, losing control over data generally because that might suggest that if you shared your data with someone else and it physically left your facility that you've therefore lost control of it. I think it's important to make very clear that we're talking about your ability to manage and control decisions regarding the data. So that's what this is about.

Paul Egerman – Businessman/Entrepreneur

Okay. So thank you for elaborating on that. So were there any questions or concerns about this concept? So, hearing 3 or 4 seconds of silence I'll move onto the next slide. Because I want to also see if we can get to question number 2 in a few minutes. And the next slide basically acknowledges that what we're simply trying to do is base our recommendation on the previous recommendations of the Tiger Team and the Policy Committee. And, basically I think it's either here or on the next slide we stated provider entity loses control over decisions regarding access to patient identifiable data then the patient should have meaningful choices. In other words, what we're trying to do here, if I'm interpreting this correctly, and hopefully you'll correct me Deven, is we want to make sure that this recommendation in effect doesn't change our previous recommendation about, you know, one of the circumstances under which patients do give meaningful consent. So, I don't know if I'm saying that correctly, but that.

Deven McGraw – Center for Democracy & Technology – Director

Yeah, I mean, I think another way to put it is to say, you know, we've looked at the issue of when, you know, consent should be applied in a different set of circumstances and we think it's a valuable point to be made here as well, you know, so much of recommendation number 1 is dependent on, you know, the institutions, you know, being accountable for the data over which they have stewardship and this just really carries it forward and says, you know, really only in those circumstances where the provider still maintains that decision making control over their data should they be able to take advantage of the kind of broadened research exemption that we've recommended here.

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

So this is Dixie. So the OHCA, I'm trying to recall our discussions about the OHCA, the OHCA would, could include an ACO but not an HIE is that correct?

Paul Egerman – Businessman/Entrepreneur

That's correct.

Deven McGraw – Center for Democracy & Technology – Director

Yeah, I mean, again depending on how an HIE is structured, but in the, you know, an OHCA is a set of organizations that hold themselves out as conducting, you know, joint activities to the public and share data, so I think that's probably going to fit with most of the ACOs that are likely to be created.

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

Most of the HIEs would say that they fit within that as well.

Deven McGraw – Center for Democracy & Technology – Director

Well, right, but I think it depends on how they're structured.

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

Keeps...

Paul Egerman – Businessman/Entrepreneur

Yeah, but the OHCA is a definition that comes from I guess is OCR, right?

Deven McGraw – Center for Democracy & Technology – Director

Yeah, it's from HIPPA.

Paul Egerman – Businessman/Entrepreneur

It's from HIPPA and it's a covered entity.

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

And I think that we should, because this is not as you pointed out before, Deven, this is not a HIPPA document that we are reviewing, we should include a definition of OHCA in our comments.

Deven McGraw – Center for Democracy & Technology – Director

Sure.

Paul Egerman – Businessman/Entrepreneur

That's a good idea. Very good idea Dixie.

Deven McGraw – Center for Democracy & Technology – Director

Very good idea.

Paul Egerman – Businessman/Entrepreneur

Okay.

Gayle Harrell – Consumer Representative/Florida – Florida State Legislator

And this is Gayle, and I also think that given what Dixie has brought up, and I think she makes a very valid point; we may want to have to make some comment if you don't put it in a letter at least verbally at the meeting to clarify that this would not apply to HIE.

Paul Egerman – Businessman/Entrepreneur

Yes.

Deven McGraw – Center for Democracy & Technology – Director

Right, again, I think we should say that in the meeting, but I think we should be clear that, you know, we're talking, we should look very carefully at the letter that we did last August about which HIEs raised our concerns and which one's didn't because HIEs come in different shapes and sizes. Like it was not HIE per se, it's HIEs that select data in such a way that the providers who contribute the data no longer have decision making control over how it's used. Right? You can have an HIE that in fact is an organizer

of a participant providers who maintain control over decisions with their data, it just depends on how it's structured, but I don't think that's a bad idea to bring up.

David McCallie, Jr. – Cerner Corporation – Vice President of Medical Informatics

And this is David. I assume business associates are covered entity extensions as per usual?

Deven McGraw – Center for Democracy & Technology – Director

Right and if they're acting under the, you know, at the direction of their covered entity.

David McCallie, Jr. – Cerner Corporation – Vice President of Medical Informatics

Yeah, okay, then I'm comfortable.

Paul Egerman – Businessman/Entrepreneur

Yep. So basically we're saying we're not intending to change what we've already said.

Deven McGraw – Center for Democracy & Technology – Director

Yeah.

Paul Egerman – Businessman/Entrepreneur

On these various topics. The next slide describes, some of you may recall at our last conference call, Richard Platt wanted to also clearly raise an issue about allowing organizations to collaborate on information, and so we put in an exemption that allows entities to collaborate, and basically we said that the entities can collaborate, you know, as long as they are either sharing for treatment purposes or to conduct these assessments as long as they remain in control over the decisions regarding how the EHR identifiable data is to be assessed, used, and disclosed. And the 2 examples, I don't know if we're going to present them, one is example was a hospital and an extended care facility that may not be members of the same OHCA but could collaborate together to try to reduce re-admissions rates, and that process could involve sharing of identifiable data and try to analyze, you know, what causes the re-admissions rate and how they can reduce them. Another example that was given was an example perhaps with a children's hospital that wants to or needs to participate in some quality assessment activity, but perhaps does not have a sufficient volume of patients and so they're collaborating with other similar institutions to give an adequate quantity of patients for the analysis to be helpful could be another example.

Deven McGraw – Center for Democracy & Technology – Director

Right, although we didn't, you know, those are actually good examples in my view, but we didn't put them in the document.

Paul Egerman – Businessman/Entrepreneur

That's right.

Deven McGraw – Center for Democracy & Technology – Director

We could if folks wanted us to.

Paul Egerman – Businessman/Entrepreneur

So I'm not hearing there is any controversy about this issue. And the next one I also, I'm taking a guess, is also not controversial. Basically, it says, you still got to do all this other fair information practices that we talked about including transparency and you know, security and all of the things that we've already talked about, this was not intended to be a carve out from any of those activities for the covered entities. So that is, I think, our entire recommendation number 1.

Deven McGraw – Center for Democracy & Technology – Director

It is.

Paul Egerman – Businessman/Entrepreneur

And, before.

Deven McGraw – Center for Democracy & Technology – Director

Good job you guys.

Paul Egerman – Businessman/Entrepreneur

We still have to do question number 2.

Deven McGraw – Center for Democracy & Technology – Director

Yeah.

Paul Egerman – Businessman/Entrepreneur

And we still have to do the chest thumping that Wes is suggesting. But before we do that is everyone satisfied with what we call question number 1? Are we ready to move onto question number 2?

Deven McGraw – Center for Democracy & Technology – Director

All right.

Paul Egerman – Businessman/Entrepreneur

So question number 2, do you want to lead us through this Deven.

Deven McGraw – Center for Democracy & Technology – Director

Yeah, so I'll go quickly through the background then, Advanced Notice of Proposed Rule Making really focuses a lot on when consent should apply to the secondary use of the EHR data for research purposes, but, you know, we know from our past work, that consent is only one of the elements of Fair Information Practices and then in fact if you're over relying on consent as the sort of linchpin of your privacy protection you can end up inappropriately shifting the burden for protecting privacy onto the patients versus the institutions, acknowledging that ONC had adopted an articulation of Fair Information, it should say Fair Information Practices, for its programs, and you know, we are also acknowledging that, you know, most patients don't really understand the difference between an entity that's a covered entity and a research entity, but will expect that there are privacy and security safeguards that apply to their data wherever it rests, and you know, we know that that isn't necessarily true and that in fact they'll be some entities that are not provider entities for example that are, you know, engaging in research, might not be covered by HIPPA, and might not be covered by the Common Rule either.

But in cases where they're covered by the Common Rule and not by HIPPA they've essentially got, you know, a requirement to get the patients consent in certain circumstances and the ANPRM does recommend the use of the HIPPA security rule for the first time, but the ANPRM really doesn't say anything at all about the full complement of Fair Information Practices. And this is the recommendations that we would make again based on our reliance on fair, on the full complement of Fair Information Practices in the work that we've done and how it leads to good policy making and this one would not be limited to provider entities. I don't think it needs, we don't think it needs to be as essentially what we're presenting to you in the way that recommendation number 1 was.

And so, basically what we're suggesting here, and this has been in your materials, this recommendation has been in the materials that have gone out to you for all of the previous meetings, and we have never gotten a chance to talk about it in any of our calls, but I have to say that either you guys got tired by the end of the document and didn't really get to vet this one thoroughly, or in fact you didn't really have any concerns about it, because it's so consistent with what we've said before, I have to admit I'm sort of hoping it's the later, but nevertheless, it shouldn't be the first time that you've read it, but it is the first time that we've had a chance to really talk about it.

So, what we're saying here is that researcher entity should be required to adopt policies and their best practices that follow the full complement Fair Information Practices regardless of whether or not a patient's consent is required to be obtained and adjust, you know, we just have some examples in here, but it's not a complete list, limiting the amount of information that is collected to what's necessary to do the research, limiting the number of people who have access to it, to those who are performing the research, adopting it, adhering to specific retention policies, adopting basic security protections that are

commensurate with, that is consistent with the privacy risks that are associated, that could be associated with the inappropriate exposure of data. Here I think it's just acknowledging, you know, that data that's fully identifiable might need a different scale of security protections than data that is less identifiable or de-identified, and then we're applauding them for actually saying in the ANPRM already that there ought to be basic security protections required and that's it.

This is just the one slide; I had to remind myself if whether we went further with this. But, this is, you know, essentially saying, you know, if you're in research it's not just about consent, it shouldn't just be about consent, it should be about full complement of Fair Information Practices and security as one piece of it as the ANPRM already recognizes, but there are other aspects too and we think that as HHS moves this proposal forward through the rule making process they ought to consider more than just those 2 elements.

Paul Egerman – Businessman/Entrepreneur

So our actual discussion, Deven, and are you at home right now currently?

Deven McGraw – Center for Democracy & Technology – Director

No that's not my dog.

Paul Egerman – Businessman/Entrepreneur

All right I was trying to see if that was sad or not.

John Houston – University of Pittsburgh Medical Center – NCVHS

That may not be your dog but is it in your house?

Deven McGraw – Center for Democracy & Technology – Director

No, I'm in the office.

Paul Egerman – Businessman/Entrepreneur

Okay.

John Houston – University of Pittsburgh Medical Center – NCVHS

If I was home you would hear my dog.

Paul Egerman – Businessman/Entrepreneur

Okay, so this is a very important issue, because in effect in this recommendation a little confusion, its recommendation number 3 but it's on question number 2.

Deven McGraw – Center for Democracy & Technology – Director

Right. Thank you Paul.

Paul Egerman – Businessman/Entrepreneur

But, basically, it's very important because this is the first time we were sort of like jumping outside of like the covered entity world and we're looking at research entities and we're saying you guys got to play by the rules also, is my very crude interpretation of that, and that it's based on in part a comment, I think it was Gayle who made it, but I think other people made it too. Well, you know, from a patient's perspective they don't know what a covered entity is versus a research organization, but they expect their data to be protected.

John Houston – University of Pittsburgh Medical Center – NCVHS

This is John Houston. You know, I think the one thing about research that at least in the context where patient consent is required for a research study the IRBs, at least the ones I deal with, are incredibly focused on ensuring that there is very clear communication with the patient regarding things like risk, what's involved in the study, all those types of matters that, but they're also trying to be very concise in how they communicate with the patient so that the patient doesn't get overwhelmed with materials related to the study and what they're actually signing up for. I guess I'm a little bit concerned that what you end

up with is so much information that may be presented in multiple methods that it could end up being more confusing for the patient. Again, if the patient has an informed consent then they got Fair Information Practices I just, you know, I think.

Paul Egerman – Businessman/Entrepreneur

But how do the Fair Information Practices overwhelm the patient?

Deven McGraw – Center for Democracy & Technology – Director

Yeah?

John Houston – University of Pittsburgh Medical Center – NCVHS

Well, because the patient when they sign up for a research study, the IRB mandates certain materials that have to be provided to the patient to inform them of things like risks and so the patient is often presented with a fair amount of, a substantial amount of information, often at times when the patient is not necessarily, well they might be in some discomfort or, you know, in a setting which may not be one where they can necessarily, it just might be a very difficult environment in which they are being presented with requests to involve themselves in a research study.

Deven McGraw – Center for Democracy & Technology – Director

But, John, the Fair Information Practices are data stewardship principles.

John Houston – University of Pittsburgh Medical Center – NCVHS

I understand that.

Deven McGraw – Center for Democracy & Technology – Director

So first of all, we're not talking about actual human subject's research where people are being consented into trials. We're talking about saying to HHS, hey you're obligations with respect to research on data shouldn't just be about consent, which you will sometimes need to get from the patient and sometimes not based on your rules, but should be about how you handle the research internally and I guess if that gets to risk, but, you know, I'm not sure that it necessarily increases, doesn't necessarily have to increase the amount of disclosure that is provided to patients just because we're asking the institutions to be more careful about the way that they use data and to pay attention to the other steps in addition to properly informing the patient in circumstances when consent is required.

That, it sort of seems odd to me that we would think that we would not say to institutions, you have an additional set of data stewardship responsibilities based on Fair Information Practices that go beyond whatever you can get the patient to agree to and are about basic good data practices that would apply regardless of whether you get the patient's consent or not, that we would reject that because we would somehow think that that would place more obligation on the patient, as opposed to relieving them of the burden of deciding whether or not the research is riskier, not relieving them, but placing all of the burden on them to make some determination of whether the institution is or isn't good with data.

John Houston – University of Pittsburgh Medical Center – NCVHS

I understand your point, Deven, I just know that, you know, the IRB takes great pain in making sure that materials that go to patients is clear, concise.

Deven McGraw – Center for Democracy & Technology – Director

I'm sure they do, but you know what, if that's all an institution does for good data stewardship I have, I think it's pretty, that would not be a good situation in my view. That really does say it's all about whether the patient understands what we're doing and not about us deciding that, you know, we're going adopt good practices and then on top of that be good with how we let patients know what we're doing.

Paul Egerman – Businessman/Entrepreneur

Yeah. So for example, John, you look at like the, I guess the 3rd bullet says adopt and adhere to specific retention policies. The way I would understand that is depending on the study, the institution would decide

how long they're going to keep the data after the study is completed and they would adhere to that. You know, it would not, there's no reason to keep the data forever, for 50 years.

John Houston – University of Pittsburgh Medical Center – NCVHS

I absolutely agree with that.

Paul Egerman – Businessman/Entrepreneur

Pardon me?

John Houston – University of Pittsburgh Medical Center – NCVHS

I agree with.

Paul Egerman – Businessman/Entrepreneur

But to me it would not require notification to the patient.

Deven McGraw – Center for Democracy & Technology – Director

Yeah.

Paul Egerman – Businessman/Entrepreneur

You know, I mean, although there might be some things that do involve notification of the patient, or if I heard your concern, is you don't want to overwhelm the patient and.

John Houston – University of Pittsburgh Medical Center – NCVHS

That's correct and I guess.

Paul Egerman – Businessman/Entrepreneur

We, I mean I share that concern. I think we all share the concern in some sense it was, another way you can interpret what we did on the first question is we said, you know, we don't want to be wasting a lot of time trying to get consents from patients on silly things and things that we think that would, you know, 99.9% they're going to say yes to, and so we don't want to overwhelm the patient but I don't see that Fair Information Practices necessarily implies overwhelming the patient.

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

This is Dixie. I totally agree with the concept that you and Deven are describing on the slide. I do have a concern about how it's presented on the slide and that's because everybody on this call I believe understands the relationship between security, privacy, and Fair Information Practices, but the people reading this may not, and I think that the way it's presented on the slide it could be interpreted, our comment at the bottom that says we applaud your, the ANPRM for recommending researchers be required to adopt basic security protections. There are people who may read this and interpret basic security protections to be the same as Fair Information Practices.

Deven McGraw – Center for Democracy & Technology – Director

Okay.

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

And I think that we would be better off saying, you know, at the top, you know, incorporate that, the Fair Information Practices extend beyond not only consent, but also beyond the basic security protections.

Paul Egerman – Businessman/Entrepreneur

Yes.

Deven McGraw – Center for Democracy & Technology – Director

Right. Okay. So the security is only one still in making that more clear.

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

Yes.

Paul Egerman – Businessman/Entrepreneur

Excellent comment Dixie, because, I mean the statement at the bottom of the slide is sincere. I mean the ANPRM they're clearly trying to do the right thing of course, and they're trying to, you know, simplify an existing process and they're trying to add privacy and security and my guess is, you know, is probably the same as your guess, when they said basic security protections they probably thought those words were the same thing or adequate as it describes what we're saying.

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

Yeah. Yes.

Paul Egerman – Businessman/Entrepreneur

So that's like a really very helpful thing, so maybe what we've got to do is sort of like promote that sentence to the top and say, you know, we applaud you for doing that and we want to clarify that basic security protections has to at a minimum include fair, what other people call Fair Information Practices.

Deven McGraw – Center for Democracy & Technology – Director

Well, no, you had me up to the last point, Paul.

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

Yeah, I agree.

Deven McGraw – Center for Democracy & Technology – Director

Those are not, you know, actually FIPs include security; it's not the other way around.

Paul Egerman – Businessman/Entrepreneur

Oh, I understand that, but the question is what do they understand, but.

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

You need.

Paul Egerman – Businessman/Entrepreneur

Maybe we can word it a little bit better, but.

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

Yes.

Paul Egerman – Businessman/Entrepreneur

The issue is, is we want to build and elaborate on the security protections to make sure that Fair Information Practices are part of the process.

Deven McGraw – Center for Democracy & Technology – Director

We want to make clear that the security provisions are not the full extent of FIPs.

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

Yeah, one piece of it.

Paul Egerman – Businessman/Entrepreneur

Correct.

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

And the consent is one piece of it, but you have a lot more to attend to.

Deven McGraw – Center for Democracy & Technology – Director

Yes.

Paul Egerman – Businessman/Entrepreneur

That's fine.

Deven McGraw – Center for Democracy & Technology – Director

Yeah, so, I mean, I think we can say that, you know, that research entities should be required to adopt, that address the full complement of Fair Information Practices regardless of whether or not a patient's consent is required to be obtained and then we have some examples, and I think we can separately make the point, one element of Fair Information Practices is good security. And we applaud the Tiger Team, we applaud the Tiger Team, here's our FIPs problem thing. We applaud the ANPRM for recommending that researchers be required to adopt security protections. How does that sound in terms of just reorganizing it a little bit?

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

Yes, just make it clear that, I mean I thought of it in terms of at the beginning, at that intro, you already have, regardless of whether the patients consent is required to be obtained, and I would just add up there and in addition to the adoption basic security protections.

Deven McGraw – Center for Democracy & Technology – Director

Right. Okay. Either way it's the same point, that's another good way to do it.

Paul Egerman – Businessman/Entrepreneur

Great. These are great comments. Do we have any other comments about this point? I have a question, as I'm looking at these examples, I don't mean to open a controversial topic, but should an example include something about transparency? Transparency about the uses of the data?

Deven McGraw – Center for Democracy & Technology – Director

It could. It could. I mean that sort of gets a little bit more to John's point about how well informed people are.

Paul Egerman – Businessman/Entrepreneur

Right. Transparency doesn't necessarily mean you have to inform the patient it just could mean that the information is available if you want to get it. Right?

Deven McGraw – Center for Democracy & Technology – Director

Yeah, I mean, in a circumstance where you don't have, where you don't have to do informed consent you arguably in following Fair Information Practices still have some transparency obligations so that people can understand who has their data and what they're doing with it.

Paul Egerman – Businessman/Entrepreneur

Yeah. Because I think transparency is important, because, I mean, to me there's a basic assumption underlying a lot of discussion that like all research is good but maybe it isn't. So.

Deven McGraw – Center for Democracy & Technology – Director

We know from history.

Paul Egerman – Businessman/Entrepreneur

People would like to know what's happening.

Deven McGraw – Center for Democracy & Technology – Director

That not all research is good.

Paul Egerman – Businessman/Entrepreneur

But maybe some people don't, some people think something is good and some people think it's less good.

John Houston – University of Pittsburgh Medical Center – NCVHS

That's the purpose of the IRB though.

Paul Egerman – Businessman/Entrepreneur

Pardon me?

John Houston – University of Pittsburgh Medical Center – NCVHS

That's the purpose of the IRB is to decide which research is good.

Paul Egerman – Businessman/Entrepreneur

Well that could be the purpose of the IRB, but it's also a value of transparency as you can find out just what these research organizations really are doing.

Deven McGraw – Center for Democracy & Technology – Director

Right. And we know that there are classes of research for which an IRB is not required to be involved and that's most of the types of research that would opine on.

John Houston – University of Pittsburgh Medical Center – NCVHS

Okay.

Deven McGraw – Center for Democracy & Technology – Director

As a Policy Committee. So, yeah, I mean it doesn't, we can add a point about, you know, being transparent about, you know, about the types of activities done with data.

Neil Calman – The Institute for Family Health – President and Cofounder

This is Neil. I have a question and I had to step away for a minute. Did you talk about the data retention issues? Because, there are requirements to retain data that is used for research that come from the research world and that many universities and many research entities require the way of substantiating the validity of the research that is put out there and published.

Deven McGraw – Center for Democracy & Technology – Director

Right. Right.

Neil Calman – The Institute for Family Health – President and Cofounder

How do we reconcile that with this statement, you know, about destroying or returning research data when it's not longer needed.

Deven McGraw – Center for Democracy & Technology – Director

Do we have a sentence in there that says destroy?

Paul Egerman – Businessman/Entrepreneur

Yeah that's where that is.

Neil Calman – The Institute for Family Health – President and Cofounder

It's, where does it say.

Deven McGraw – Center for Democracy & Technology – Director

Is it in the document and we don't put it in the slide?

Neil Calman – The Institute for Family Health – President and Cofounder

... in here specific retention policies and return or destroy the data upon expiration of a retention period.

Deven McGraw – Center for Democracy & Technology – Director

Okay so that's the, that must be in the document and we don't, we we're trying to keep the slides to a.

Neil Calman – The Institute for Family Health – President and Cofounder

Okay, it's in the example.

Deven McGraw – Center for Democracy & Technology – Director

Right. Right. No I get it. I, you know, this is going to create confusion, so all I was trying to do Neil was to create some examples.

Neil Calman – The Institute for Family Health – President and Cofounder

Okay.

Deven McGraw – Center for Democracy & Technology – Director

Of Fair Information Practices, but if you, but if it sounds like that's going to create some confusion with, you know, whether we're trying to override existing law, which we would not do, so I, you know, I can certainly take that piece out if it's going to just raise confusion. Again, we're just trying to provide examples of Fair Information Practices, and we would of course site to, you know, ONCs model since it's adopted, but we, you know, could also site to others. So.

Neil Calman – The Institute for Family Health – President and Cofounder

I guess it's okay because it basically says adhering, I guess adhering to retention policies but those policies are sort of set locally, but, I don't know, it may not be, it might not have been confusing for anybody other than me, so.

M

I think it is going to promote discussion about, I mean, retention. A lot of people say well they never want to read, never want to get rid of research data.

Deven McGraw – Center for Democracy & Technology – Director

I know.

M

And you hear about these long-term studies, these studies that when you look back at data from 30 years ago and so I think this might provoke more discussion when you really don't want to talk about.

Paul Egerman – Businessman/Entrepreneur

Well maybe should we drop it as an example?

M

Yes.

Deven McGraw – Center for Democracy & Technology – Director

Yeah, which I'm actually fine with. I mean, you know, data retention is a big and complex issue and it wasn't, it definitely was not our intent to try to get into a robust discussion about which Fair Information Practices would apply and in which circumstances and what specific policies would look like, and so if it just raises more questions than it answers I'm fine with dropping it.

M

You'll get...

Deven McGraw – Center for Democracy & Technology – Director

...of examples, it's not intended to be exclusive.

Neil Calman – The Institute for Family Health – President and Cofounder

Okay.

Paul Egerman – Businessman/Entrepreneur

Any other comments? Well not hearing any other comments I think that wraps up these 2 questions and in the category of what Wes suggested, to use a different metaphor, doing a victory lap this is really great work.

Deven McGraw – Center for Democracy & Technology – Director

Yeah.

Paul Egerman – Businessman/Entrepreneur

On a challenging topic and it's also great work in the sense that we stayed very focused on the EHR data aspect of the topic because there is a lot of side discussions that we could have done that are also very interesting and compelling, so I just think this is terrific work. And I just want to say thank you to everyone, thank you to Deven, and I don't know if Rich Platt was able to join but...from Rich and John Houston who gave significant experience with the IRBs and was very helpful, and thanks to everybody, Judy, great, great examples and you know, David and Neil, Leslie terrific. You have anything else you want to add.

Deven McGraw – Center for Democracy & Technology – Director

No, I thought I heard Rich trying to.

Richard Platt – Harvard Medical School – Professor & Chair

Yeah I was just going come clean and say that was my dog.

Paul Egerman – Businessman/Entrepreneur

Pardon me; I didn't hear what you said.

Richard Platt – Harvard Medical School – Professor & Chair

I was going to admit that that was my dog that was barking.

Paul Egerman – Businessman/Entrepreneur

Okay. Well then I'll take back all the nice things we said about you.

Deven McGraw – Center for Democracy & Technology – Director

I like that, that's terrific, thanks. So the process, what happens now is that we, you know, incorporate the feedback that we got from you all into the materials that we prepared for the Policy Committee for Wednesday, we present it to them, everybody crosses their fingers in hopes that we have a robust discussion, but at the end of the day get essentially what we've asked for and then ideally a letter will then, the transmittal letter of the recommendations will be submitted to HHS per our usual channels but also made sure to be part of the comments that are included for the ANPRM.

We will, you know, for those of you who are comment wizards, you know, that we have to sort of, we will have to go back through the recommendations and probably tag them with the specific questions that, you know, that we're asked in the ANPRM so that we make sure that its relevant and by that I mean not changing at all the substance of what we said but making a note about which question or questions we think that the recommendation is relevant to, and we will be doing that. But that's largely an administrative exercise, but in case people were concerned that is customarily what you need to do to make sure that your materials are relevant to the regulators and we will be doing that as well. So that's, with any luck we will not be asked by the Policy Committee to continue to deliberate out any particular questions since we don't actually have really any time to do, we have a meeting towards the end of September before the commentary closes, but there is no Policy Committee meeting necessarily to re-vet any additional answers we provide, so I think ideally the process, we would essentially hope to conclude this on Wednesday. I guess we should reserve for the possibility that there's a chance that there might be some additional matters that we might have to weigh in on and we would do that on our next call. So.

M

Great.

Deven McGraw – Center for Democracy & Technology – Director

All right. Judy, you want to open up the lines for public comment?

Judy Sparrow – Office of the National Coordinator – Executive Director

Yeah. Thank you everybody. Operator can you check with the public and see if anybody wishes to comment.

Caitlin Collins – Altarum Institute

Yes. If you are on the phone and would like to make a public comment please press *1 at this time. If you are listening via your computer speakers you may dial 1-877-705-2976 and press *1 to be placed in the comment queue. We do not have any comments at this time.

Judy Sparrow – Office of the National Coordinator – Executive Director

Okay, well thank you and thank you everybody for this Friday afternoon work.

Paul Egerman – Businessman/Entrepreneur

And thanks again.

M

Thanks everybody. Great job.