Privacy & Security Tiger Team
Draft Transcript
August 5, 2011

Presentation

Judy Sparrow – Office of the National Coordinator – Executive Director
Good afternoon, everybody, and welcome to the Privacy and Security Tiger Team. This is a federal advisory call so the public will be able to make comments at the end of the call, and just to remind the workgroup members to please identify yourself when speaking.

I'll do a quick roll call; Paul Egerman?

Paul Egerman – Software Entrepreneur
Here

Judy Sparrow – Office of the National Coordinator – Executive Director
Gayle Harrell?

Gayle Harrell – Florida – House of Representatives
Here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Meredith Taylor for Carol Diamond?

Meredith Taylor – Markle Foundation – Director of Health
Here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Judy Faulkner?

Judy Faulkner – Epic Systems – Founder
Here.

Judy Sparrow – Office of the National Coordinator – Executive Director
David McCallie?

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Neil Calman?

Neil Calman – Institute for Family Health – President & Cofounder
Here.

Judy Sparrow – Office of the National Coordinator – Executive Director
David Lansky? Dixie Baker?

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Here.

Judy Sparrow – Office of the National Coordinator – Executive Director

Christine Bechtel or Alice …? John Houston?

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
Here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Wes Rishel? Rich Platt?

Richard Platt – Harvard Medical School – Professor & Chair
Here.

Judy Sparrow – Office of the National Coordinator – Executive Director
John Granit? Leslie Francis?

Leslie Francis – NCVHS – Co-Chair
Here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Linda Koontz? Christina Hyde?

Christina Hyde – OCR
Here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Verne Rinker?

Verne Rinker
Here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Joy Pritts?

Joy Pritts – ONC – Chief Privacy Officer
Here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Did I leave anybody out? All right, with that, I'll turn it over to Paul Egerman.

Paul Egerman – Software Entrepreneur
Thank you very much, Judy. This is Paul Egerman. As Judy went through the roll call one name you did not hear was my colleague, Deven McGraw. Deven is traveling today so she will not be attending this call.

The tiger team, to briefly remind everybody, is basically a subcommittee of the HIT Policy Committee that has been created to address various privacy and security issues related to ONC (Office of National Coordinators) activities. At the end of this call there will be an opportunity for members of the public to make comments, and if there are any members of the public listening—I believe there's almost always somebody or several people in our public calls—I wanted to thank you for your interest in our work, especially on a Friday in the summer. I want to assure you that your comments are very much appreciated and we pay very careful attention to any comments made by members of the public so please feel free to give us your feedback.

This afternoon, or for those of you on the west coast this morning, we will be starting a new topic. HHS and the Office of Science and Technology Policy has issued an ANPRM, and you may want to know what the A stands for, the A stands for Advanced. It's sort of, the way I understand it, it's sort of like an advanced warning or discussion that an NPRM will be issued in the future and this is a way that the two

really gather input and information to help formulate the NPRM, and the ANPRM is on the topic of research, which is an absolutely fascinating topic. What we would like to do with this tiger team is to go through what's in the ANPRM and also to formulate some recommendations that we might have about research uses, really of data, because we need to remember that our focus should be on ONC's programs and also privacy and security. The focus of the ANPRM is much broader in terms of research and safety of patients and individuals involved with research.

Here is what we would like to do as an agenda for today's call or goals for the call. We wanted to … and sort of like foundation material first so that we all understand the basic issues, so the first bullet is to really have some review of relevant aspects of what's call Common Rule and also relative aspects of HIPPA and what HIPPA says about the research usage of data. Secondly, what we'd like to do is briefly review the relevant provisions of the ANPRM; and the third thing we want to do is also very briefly review our previous tiger team and HIT Policy Committee recommendations that perhaps might be helpful to the discussion. If we somehow manage to get through all those things in today's call, then we will start to talk about how are we going to frame our discussion, what are the questions that we want to answer?

Now, in doing this whole discussion I first want to tell you what the timeframe is. The responses on the ANPRM are due September 26th. We have a policy committee meeting a bit earlier, I think middle of September or early part of September and so we really, right now, only have two more meetings after the current meeting before the Policy Committee meeting so that gives us a little bit of a timing challenge for our discussion.

When Judy Sparrow did the roll call you may have noticed a new name certainly, which is Richard Platt. We're very pleased that Dr. Platt has been able to join our tiger team for these discussions. We added Richard Platt because we felt it very much important that we have people on the team who are doing this. Who are doing research using patient data, and we might try to get one or two other researchers involved.

Before we get started, I said quite a bit, let me see if people have any comments or questions and if Linda or Joy wants to correct anything that I said, make sure I got it all correct.

Joy Pritts – ONC – Chief Privacy Officer
Sounds pretty good, Paul.

Paul Egerman – Software Entrepreneur
Okay, I was in the vicinity of what an ANPRM is supposed to be.

Joy Pritts – ONC – Chief Privacy Officer
Well, there's never any promise that anything ever results in an actual rule here but that's close.

Paul Egerman – Software Entrepreneur
And I got instantly an email that Wes Rishel has been able to join the call so welcome, Wes, and does anybody else have any questions? … any questions I'm going to ask Linda to dive in. So, again, the purpose of this part of the discussion is going to be to give us like some foundational information to help us with our deliberations on this topic to make sure we all have the same set of materials. So Linda will first take us through the Common Rule, then the relevant aspects of HIPPA, and then the relevant aspects of ANPRM, and if it's okay, Linda, what I'll probably do is to ask you to pause after each section and see if people have questions.

Joy Pritts – ONC – Chief Privacy Officer
Okay and before you do that, Linda, we also have on the line with us, Christina Hyde from OCR who's done an awful lot of work in this area and so if you get to a point where you need clarification on this she's available to give us some assistance.

Linda Koontz – MITRE – Principal Information Systems Engineer, Privacy
Excellent. Christina, feel free to chime in where appropriate. Okay, are we ready to start, Paul?

Paul Egerman – Software Entrepreneur
Yes, we are, Linda.

Linda Koontz – MITRE – Principal Information Systems Engineer, Privacy
The Common Rule first, these are the regulations which govern most federally funded research on human subjects, and there's a very long history here. The first basic regulations on human subjects' research were established in 1974, and then the Common Rule followed sometime afterward and was established in 1991. These rules were designed to address primarily clinical trials, and they focus on protecting human subjects from physical risk as opposed to information risk, which are becoming more prevalent in research. This includes research that uses identifiable information, and the rules framework is really based on two foundational concepts. The first, informed consent of the research subject when there is more than minimal risk; and also, independent review and approval of research by an institutional resource research board or IRB.

First of all, the IRB membership and role; it's composed of five members of various backgrounds from the institution and includes at least one member who is not affiliated with the institution. The IRB reviews and approves all research activity. They require documentation of informed consent or they may waive requirements where certain conditions are met, so they can actually waive the requirements for informed consent. They also currently conduct continuing review of research and they're to do that not less than once per year.

Also, HHS has established a list of categories of research that they determine represent no more than minimal risk and this research then can be reviewed in an expedited review where a single IRB member is responsible for conducting their review. In addition, there are six categories of research that are exempt from the required IRB review and one that I would just like to call out is the fourth category and that is the study of existing data and that could be data that came from EHRs or any other kind of source.

M
Question, I assume that means a study of existing data that does not require any additional contact with the subject, it's kind of passive only. It doesn't involve any new contact?

Linda Koontz – MITRE – Principal Information Systems Engineer, Privacy
Yes and that is my understanding. Christina and Joy, you can correct me if I'm not quite right on that. No, I guess we're okay.

M
I had a question about that also, existing data means data that exists from research already has or just existing data anywhere?

Linda Koontz – MITRE – Principal Information Systems Engineer, Privacy
I'm sorry. Does this have to be data that's existing from research? No.

M
In other words, if I'm a researcher do I have to already have the data to call it existing data or I can just say, "Well, the data exists at University of Pittsburg so I'll get it from them and I'm exempt from the IRB because—"

Linda Koontz – MITRE – Principal Information Systems Engineer, Privacy
Christina, do you want to field that—?

Christina Hyde – OCR
Well, I'm not sure exactly what the question is.

Joy Pritts – ONC – Chief Privacy Officer

They're asking about what existing information means and—I'm just going to throw the question back at you because I'm not 100% sure but I think its information that is collected for purposes other than research.

Christina Hyde – OCR
Well, there are a lot of things going on in the ANPRM but when they're talking about existing data and using that for secondary uses it could be data that's been collected either for a research purpose or for a non-research purpose.

Richard Platt – Harvard Medical School – Professor & Chair
This might be worth doing some offline clarification because my experience is quite different from this but it's every IRB that I've met has considerable interest in revealing and improving proposed uses of medical record information, unless it is has already extensively been identified. I think it … the sense of this slide, so some clarification would be worthwhile.

Gayle Harrell – Florida – House of Representatives
I also have some concern. Does this essentially mean that if say Kaiser has a database of all their patients that without permission/consent or even knowledge that someone who was doing research say on cancer could go and data mine that?

Richard Platt – Harvard Medical School – Professor & Chair
I can tell you from personal experience that doesn't happen. I'm sure Kaiser's IRBs review all such uses of the electronic heath record data so—

Gayle Harrell – Florida – House of Representatives
… something already set up that requires that; however, if you were say at Martin Memorial Hospital could I go in, if I'm doing research, because they had electronic systems, go in and data mine all their records without any review by an IRB?

Richard Platt – Harvard Medical School – Professor & Chair
Well, you guys, I think, are misunderstanding what exempt means and also the fact of the matter is that just because an organization—that there's certain processes in place to look at existing data doesn't mean that anybody off the street can simply walk in and look at that data. The IRBs by mandate are required to ensure the research communities are properly trained and they have oversight of that research community.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
The other point here—and I'm on IRB and have some experience here too and mine is the same as Dr. Platt's. But I would also point out that the Privacy Act itself prohibits the use of data that is collected for one purpose to be used for another purpose, so by exempting that really would go against the privacy rule itself.

Richard Platt – Harvard Medical School – Professor & Chair
I think it is not worth spending a lot more time on this point because as stated here I'm pretty sure it doesn't satisfy—this is not the interpretation that most IRB are applying. … exempt use of data from the EHRs.

Paul Egerman – Software Entrepreneur
These are helpful comments so what's stated here—let's see if I got this right. What's stated on this screen seems to be inconsistent with your experience, Richard Platt and also with your experience Dixie—

Linda Koontz – MITRE – Principal Information Systems Engineer, Privacy
Paul, I think you need to make a distinction between what—well, there's a distinction between what the rule requires and what the actual practice is so I wouldn't say that it's inconsistent. It's just that the practice goes beyond what the rule requires.

Paul Egerman – Software Entrepreneur
So you think this is an accurate statement of the rule though?

Linda Koontz – MITRE – Principal Information Systems Engineer, Privacy
Yes.

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
I don't know if it is or not. My experience has been that one of the human subject protection that the IRB is concerned about is one of privacy and so an IRB doesn't, in fact, at least at my institution, always reviews any request for data that is on an identifiable basis or even if it's partially de-identified. They would have to provide some approval in order for a researcher to have access to it. I always believed that was consistent with the Common Rule.

Judy Faulkner – Epic Systems – Founder
This is a fascinating topic because when you consider the dashboards and reports that we do for the quality review and for population management you get all sorts of information that allows you to drilldown to the patient level.

Richard Platt – Harvard Medical School – Professor & Chair
But that's not research. Research is—

Judy Faulkner – Epic Systems – Founder
What's the definition of research and maybe we can get past this.

Paul Egerman – Software Entrepreneur
It's a great question, Judy. What the definition of research? We're actually going to come to that in a minute. I want to make sure we get through all of this process so getting back to this discussion. This is like a critical issue and it seems like what is happening in practice may be better than what is happening in terms of what is stated on—

Joy Pritts – ONC – Chief Privacy Officer
The slides, I believe, are set up with Common Rules Privacy Rule and so any IRB will be, although they're not direct—we're jumping ahead here, I believe, because I haven't looked at the slide but there are multiple rules that you have to comply with, so I mean and—well, I won't have editorial comment on that but that's one of the issues that's presented in the ANPRM.

Paul Egerman – Software Entrepreneur
Okay, that makes sense. Why don't we continue on the deck? So this is what it says on the Common Rule then, right?

Linda Koontz – MITRE – Principal Information Systems Engineer, Privacy
Yes and at the risk of starting the conversation all over again I will say that most research requires informed consent but there are types of research and we did talk about pre-existing data are exempt from the rule and therefore there's no requirement for informed consent. In addition, an IRB may waive any requirements for consent that might otherwise apply and there are a couple conditions under which the IRB can do this. It's for certain research that's conducted or approved by the state and local officials or it's when the IRB documents that the research involves minimal risk that a waiver won't adversely affect the rights or welfare of the subjects, that the research could not be practicably conducted without the waiver and where the subjects, as appropriate, will be provided with additional pertinent information after their participation in the research.

Researchers are not currently required by the Common Rule to adopt any particular security measures. However, some researchers that are covered entities under HIPPA—and we're going to talk about HIPPA in just a bit—may also be covered by the HIPPA Security Rule, and I will point out that the disclosure of a limited data set to a researcher by a covered entity may require a data use agreement.

Gayle Harrell – Florida – House of Representatives
I have a question. … information practices come in to play here?

Linda Koontz – MITRE – Principal Information Systems Engineer, Privacy
In terms of the Common Rule?

Gayle Harrell – Florida – House of Representatives
Yes.

Linda Koontz – MITRE – Principal Information Systems Engineer, Privacy
The Common Rule is not—because, as I said, it's mostly about physical risks and clinical trials and that sort of thing it really doesn't address the informational risk and it's not really based on fair information practices. Maybe Joy or Christina wants to add to that.

Joy Pritts – ONC – Chief Privacy Officer
Well, it does touch on privacy but it was not primarily written to address how informational risk—but as Linda will continue to explain it does interact with the privacy rule, which does address those risks, so I would—

Christina Hyde – OCR
I think the charge to the IRB currently is to examine the confidentiality as part of their review of the research. That's certainly not as specific as what the privacy and security rules require with respect to data.

Paul Egerman – Software Entrepreneur
Who was just speaking?

Christina Hyde – OCR
This is Christina.

Paul Egerman – Software Entrepreneur
Hi, Christina, I just want to ask everybody to state your name before you speak for the listeners and the public, so very helpful. As Joy pointed out there is more than one rule involved and Linda just finished the Common Rule. She's about to start research rules under HIPPA. Where there any other comments or questions about the Common Rule before we dive into this?

Leslie Francis – NCVHS – Co-Chair
I would like to make one other comment, which is that the text flows exemption four also requires the information by recorded in such a way that it is not identifiable.

Christina Hyde – OCR
That's an important point, so it's not access to all identifiable data that's exempt from the Common Rule but one thing I would point out is that what's identifiable under the Common Rule is different from what's identifiable under the Privacy Rule.

Leslie Francis – NCVHS – Co-Chair
That's correct but that's why some IRBs get concerned because what they want to do is ensure that when folks record data they're not—under exemption four somebody could actually see identifiable data and record it in such a way that it is not identifiable and that's where IRBs walk into the mix. They don't review it. I mean they want to make sure you're doing this data that is identifiable but their concerned about who looks at it.

Linda Koontz – MITRE – Principal Information Systems Engineer, Privacy
Is it okay to go ahead to Research Rules under HIPPA?

Paul Egerman – Software Entrepreneur
Absolutely.

Linda Koontz – MITRE – Principal Information Systems Engineer, Privacy
Okay, we're on slide eight. Obviously, HIPPA applies directly only to covered entities, which are providers, plans, healthcare clearinghouses and to business associates conducting research on their behalf. It covers only protected health information, which is identifiable, and some entities may be subject to both HIPPA and the Common Rule. HIPPA directly impacts many researchers because it limits how covered entities that create and maintain PHI may disclose it to researchers because as you remember HIPPA has to do with basically a lot of rules about the disclosure of PHI.

Research is distinguished from healthcare operation—

Christina Hyde – OCR
Can I just make one point of clarification on the prior slide? Researchers are not business associates generally by virtue of their conducting research. They may be business associates of a covered entity because they've been hired to de-identify data or create a limited data set, for example, but not by virtue of doing research.

Neil Calman – Institute for Family Health – President & Cofounder
Let me ask a question because this is very real to us and this is coming up all the time so I think some practical examples might be useful. So a university is now doing a study comparing quality reports that are generated out of our electronic health records with chart reviews of actually looking at the data in each patient's chart to see whether or not it validates what was printed. In other words, comparing the accuracy of those two ways of generating quality reports, so in order to do that they're entering into—just like they would have done on paper charts—they're entering into each person's electronic health record so it identifies the person. They're entering into their records. They're looking to see do they have an A1C or a blood pressure and all that and they're recording it with the generated report, so according to this that wouldn't be allowed but they're actually assessing personal health information at the time they're doing that. Now, of course that's been approved by the IRB so where would that stand in relationship to these kinds of rules?

Christina Hyde – OCR
A couple of things, I think, are going on there. One, is you may be raising the issue of what is research versus what is a quality activity that's done on …—

Neil Calman – Institute for Family Health – President & Cofounder
This is purely for research.

Christina Hyde – OCR
Purely for research? Just because you have an outside entity who may not be a business associate because they're doing a research function you still need to comply with the Privacy Rule in terms of how that person has access to the identifiable data for research purposes whether it's with the individual patient authorization or with a waiver by an IRB or a privacy board. The fact that they may not be a business associate doesn't obviate the need for the other protections in the rule to apply to the disclosure for research purposes.

Richard Platt – Harvard Medical School – Professor & Chair
That all sound fine but I think the notion that this is purely for research probably deserves further evaluation because it seem extraordinary that an institution that would participate in such an activity wouldn't intend to use the results to improve operations and that gets at the issue that Paul was raising about thinking about what the definition of research ought to be.

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
Practically speaking, working for a very large healthcare organization, the definition of research and quality is something that—I think it's well understood by those individuals that are involved in research

and quality and nothing prevents research to be used for quality purposes after the fact. The opposite though is a much more difficult one. When somebody does quality to turn it into research is not necessarily an easy thing to do but nonetheless I think that the IRB's very careful to—at least the one I work with—is very careful to delineate what's quality and what's research and to make sure that one isn't inadvertently characterized as another.

Neil Calman – Institute for Family Health – President & Cofounder
I think that's what you said that's really important because one of the things that happens is you can do anything under the guides of quality, which gets you into some dangerous territory in relationship with not following all of the requirements that it would be if you called it research, and I know that a lot of people who've brought projects to the IRB would like to call them quality improvement projects but at their face they're really research projects and they have to go through that type of review.

Christina Hyde – OCR
I do think there is a question in the ANPRM about drawing an appropriate distinction between quality and research. I'm not quite sure I'm putting my hands on it at the moment but to the extent that—that's one of the areas that the ANPRM requests feedback—

Richard Platt – Harvard Medical School – Professor & Chair
Right, it's questioned from before and I suppose my question for this group is that within bounds for this discussion?

Paul Egerman – Software Entrepreneur
The answer is yes. This not quite within bounds now, in other words what we're going to do is we're going to go through some of this foundational material but then we'll be discussing whether the question we want to respond to and it does seem like this might be one of those questions that we might need to respond to or might be helpful if we responded.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Since this is very foundational as you've pointed out I wanted to tell you guys I found paragraph four in the Common Rule. The one that was asserted that it exempted pre-existing conditions, and what it actually says is, "Research involving the collection or study of existing data, documents, records, pathological specimens or diagnostic specimens if these sources are publically available or if the information's recorded by the investigator in such a manner that subjects cannot be identified directly or through identifiers linked to the subject," so it is consistent with HIPAA.

Christina Hyde – OCR
Well, not quite because what we consider de-identified under our rule—they would consider—let me put it this way—a limited data set of information which does contain some identifiers to be exempt, so they would consider that not identifiable. On our end we do consider that identifiable. We don't require authorization or a waiver we require a … agreement. My point is only that there are some differences in what's considered identifiable under both rules.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Okay, I just wanted to make clear it doesn't say that pre-existing data is exempt.

Christina Hyde – OCR
Right, yes, exactly.

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
My apologies but in looking at DHHS definition of research one sentence I think is important. It says, "It's a systematic investigation including research, development, testing and evaluation designed to develop or contribute to generalizable knowledge," and I think that's one of the differences between quality assurance and research is quality assurance is typically focused on improving processes, practices, whatever, within an institution whereas research is really focused on developing and contributing to generalizable knowledge.

Paul Egerman – Software Entrepreneur
Helpful comments, again, what we want to do right now is make sure we have similar foundation of knowledge so we went through some of the Common Rule and right now Linda is going through some of the research rules under HIPPA and you're on slide nine. I'm going to ask that you continue please.

Linda Koontz – MITRE – Principal Information Systems Engineer, Privacy
Thank you and this goes actually with the previous comment that was made that research is distinguished from healthcare operations, which includes quality assessment and improvement activities as long as the primary purpose of such activities is not to obtain generalizable knowledge.

Paul Egerman – Software Entrepreneur
Okay so this is helpful. It may impart respond to some of Judy's questions but it may not but let's continue on.

Linda Koontz – MITRE – Principal Information Systems Engineer, Privacy
Okay and the release of information of fully identifiable data does require an authorization in most cases, and as it says here that the authorization needs to be in writing, specific to the particular research project. The note here is that pending regulation change would allow individuals to provide more general consent to research uses of their PHI, and that refers to some of the proposed changes in the notice that we'll talk about in a little bit. A covered entity can release PHI for research purposes also if it receives documentation that an IRB or a Privacy Board has approved a waiver of the requirement. Authorization's not required in certain instances and that includes: purposes that are preparatory to research, research on decedents, and the release of a limited data set.

Paul Egerman – Software Entrepreneur
So research on decedents that means if somebody dies the data can be released and nobody has anything to say about it?

Linda Koontz – MITRE – Principal Information Systems Engineer, Privacy
Yes.

Christina Hyde – OCR
That's to align the HIPPA Privacy Rule provisions with the Common Rule then decedents are not human subjects under the Common Rule but on the Privacy Rule side we do require some representation from the researcher that they are in fact just doing research on decedents and requesting the projects house information about decedents.

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
Regarding decedent research as long as one member of the cohort's alive the IRB will take jurisdiction typically so everybody has to be dead in order for decedent research to avoid IRB oversight.

Paul Egerman – Software Entrepreneur
Well, hopefully this drug that they're studying didn't kill everybody.

Linda Koontz – MITRE – Principal Information Systems Engineer, Privacy
Okay, next slide. Covered entities may use and disclose a limited data set for research purposes, and this is data, as you know, which is stripped of names and other identifiers but it's still considered potentially re-identifiable, and it requires a data use agreement and a commitment not to re-identify on the part of the researchers. When we go to re-identify data, as you know, it's not largely subject to regulation by HIPPA. The de-identification standard is that there's no reasonable basis to believe the data can be used to identify an individual, and there is no requirement of a data use agreement or a commitment not to re-identify. Although, we note there that a covered entity would not be able to re-identify.

This is just a reminder, I think most people know this, there are two methods under HIPPA that can be used to de-identify information. First, is a statistical method where there's someone who's knowledgably

about statistical methods, and they determined that the risk is very small that the information could be used to identify an individual; and then there's also the safe harbor method, which requires the removal of 18 specific data elements, and the data holder must not have actual knowledge that the data alone or in combination with other data could identify an individual. Entities may assign a code to allow de-identified data to be re-identified as long as the code is not shared with the researchers.

That's the end of the section on HIPPA and Research Rules so we'll pause here for a moment to see if people have additional questions. I think we can go ahead with the proposed changes to the Common Rules that are articulated in the ANPRM.

The focus is on changes to the Common Rule but also there is a bit of a desire expressed in the notice to harmonize and streamline different research rules and those in particular would be the Common Rule and HIPPA. There are quite a number of changes that are proposed in the Advanced Notice and we don't intend to cover all of those here. The notice itself is almost 100 pages but for the tiger team and for the Policy Committee, we—and that actually means not me it means the tiger team chairs—propose focusing on the provisions with a direct impact on ONC programs and that's the rules surrounding research uses of health information initially collected for another purpose and by that, that could be, for example, research use of information initially collected by providers for treatment purposes.

There's also in the relevant advanced notice provisions there are some changes to the scope proposed just for background purposes. They are proposing to expand the scope to any institution receiving federal funds even if the particular research is not supported with federal funding whereas now it applies only to federally funded research and some other categories. Again, the advanced notice also talks about a desire to harmonize HIPPA with other relevant rules governing research.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
I have a question, whereas healthcare is actually legally governed by the state versus federal—is research a state regulated process or is it more a federal regulated process? Activity I should say, not process. In other words, if states have different regulations around research … and Common Rule, let's say.

Joy Pritts – ONC – Chief Privacy Officer
Can I jump in on that one?

Linda Koontz – MITRE – Principal Information Systems Engineer, Privacy
Oh, you sure can.

W
Please do.

Joy Pritts – ONC – Chief Privacy Officer
Research is primarily governed at the federal level. There are some states that have specific rules governing researchers but for the most part the state laws that deal with research are more on the disclosure side as to when a provider or a plan may disclose information for research versus directly imposing restrictions on researchers as to how they may conduct their activities, and if John or anyone on the phone who is a researcher has a different experience we'd love to hear from them on that.

Richard Platt – Harvard Medical School – Professor & Chair
I think that's largely true—

Joy Pritts – ONC – Chief Privacy Officer
Right, there's always an exception isn't there?

Richard Platt – Harvard Medical School – Professor & Chair
But in fact the Brookings Institution actually commissioned a giant … that tried to summarize the 50 states sort of variation in practice. If you dig down there is a lot of variability that investigators need to be aware

of. If you want just one example it's very, very difficult in California to do any research involving a prisoner even if that prisoner is hospitalized in a general purpose hospital. So if you were doing a study involving everyone who's admitted to Hospital A in California you actually have to do a fair amount of work to make sure that there aren't any inmates who happened to have been admitted to the hospital because they're excluded from that research. Just sort of one antidote but there is actually a lot of sort of fine details that …

David McCallie – Cerner Corporation – Vice President of Medical Informatics
I have another question, the advanced notice of the rule changes would that just affect the Common Rule or could it also affect provisions in HIPPA?

Christina Hyde – OCR
The advanced notice of proposed rulemaking—I guess the next step would be a proposed rule to revise the Common Rule, the HHS Team and subject protection regulations and others, but there is a recognition in the ANPRM that depending on what the rules will look like at the end that there will also need to be changes for harmonization purposes to other rules including HIPPA.

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

Linda Koontz – MITRE – Principal Information Systems Engineer, Privacy
Again, there are some changes to the rules on existing data where that does not require IRB review, and I realize now when I look at these bullets that these may be confusing to the group. I'll call on Christina, if she can help me clarify but the point here is the proposed rule proposes to still track research that's not subject to IRB review, and they want to do that by registering, having the researchers do some kind of brief form with the IRB and registering that research.

Christina Hyde – OCR
There is a question in the ANPRM on whether there should be some registration with the IRB or research office where there's research on de-identified data as well. For purposes of auditing whether the restriction on re-identification has been complied with.

Linda Koontz – MITRE – Principal Information Systems Engineer, Privacy
Thank you. Okay, just a little bit more detail on pre-existing data and informed consent for the use of pre-existing data which was originally collected for non-research purposes. The ANPRM reiterates the existing rule that written consent is required only if researchers obtain information that identifies the subjects thus no consent is required for research using the limited data set or de-identified information, and the notice does seek comment on whether consent should be required here, and if so, what type of consent.

For the category of existing data that was originally collected for research purposes the advanced notice is proposing a new requirement that consent would be required regardless of whether or not a researcher obtains identifiers, and so this is different than what the current requirement is. It also envisions that consent for future research would be typically obtained from the subject at the same time as consent for initial research, and this is another area where the advanced notice requests feedback on this consent rule. They are also proposing a direct prohibition on researchers de-identifying information that they have received in de-identified format, and last, the advanced notice and proposed rulemaking proposes baseline securities measures, which would vary depending on the identifiability of the data, and they're proposing that the HIPPA standards for individually identifiable information, a limited data set and de-identified information be adopted. They are also proposing that research involving identifiable data in limited data sets could be required to adhere to the data security standards modeled on the HIPPA Security Rule, and they do have a provision that data could be considered de-identified or in limited data set form even if researchers see but they don't record in the permanent file the identifiers. In addition and finally, they're considering additional enforcement tools such as audits, and we'll pause here.

Paul Egerman – Software Entrepreneur

Who would do the audit?

Linda Koontz – MITRE – Principal Information Systems Engineer, Privacy
I don't believe—Christina can correct me on this but I believe one of the things they're asking, who would be the proper people to do the audit? That's one of the questions they're asking.

Christina Hyde – OCR
Right, its question 66, I believe, but it's focused on which entities within the institution conducting the research should be given the oversight authority to conduct the audit.

Paul Egerman – Software Entrepreneur
Let me first state, Linda, great job. That was a terrific job of presenting a lot of material and very briefly summarizing it. Before we start talking about the tiger team and our response what questions do we have for Christina and what appears to be a really good group of experts who seem to know this material very well?

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Back on the previous two, the distinction between data collected for research and for non-research am I understanding that right that if data was collected as part of routine medical care that would fall under your non-research purpose as opposed to someone who is actually recruited into a trial that would be the "for research purpose?"

Linda Koontz – MITRE – Principal Information Systems Engineer, Privacy
That's correct.

Christina Hyde – OCR
The ANPRM is—proposing is not really the right word but putting out there a construct where there would be different consent rules based on whether you're doing research on information that was collected for non-research purposes versus research purposes, and that was the distinction between the two slides, which I'm happy to talk about a little bit more if you would like me to.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Yes, could you please?

Christina Hyde – OCR
Sure, so in terms of written consent for future research for material collected for non-research purposes that would essentially follow the rules today, which ends up in construct broadly speaking in terms of when consent is required versus not. So if it's identifiable information or if it's biosustance, then it would require consent and this is identifiable based on how HIPPA defines identifiable, and they're supposing that consent could be obtained at the time of initial collection, so it would be sort of a broad future use consent.

Now, if the researcher's coming back and wants to use just a limited data set or de-identified information then no consent would be required for that use, that secondary use. If, however, the future research purpose is looking to use data or specimens that were originally collected for research purposes then the consent would be required regardless of whether the use is looking to use de-identified information or even a limited data set. I guess the purpose of that is where you have told a research participant in the original consent at the time of the initial research that you would only use their data for certain purposes that is then respected downstream even if the data is later de-identified.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
That would be a change.

Christina Hyde – OCR
That would be a change, yes, and the ANPRM recognizes that.

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
Just a question though, I know we had talked about waivers a little while back, waivers would still be a … available so that an IRB could still issue a waiver that would allow the researcher to use that information subsequently without patient authorization, again, as long as they got a waiver, correct? Would that be part of it?

Christina Hyde – OCR
There is a discussion of waivers and I think it is contemplated that there would still be waivers under this construct but it doesn't specify the rules for those waivers.

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
Okay there are notes this is a lot of discussion on waivers then in this ANPRM?

Linda Koontz – MITRE – Principal Information Systems Engineer, Privacy
Not with respect to the issue that you raised, John.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
I'm curious whether it's possible to know why the sort of the assumption that use de-identified data doesn't jeopardize the subject. Why is the rule being tightened up in that regard? Is it distrust for de-identification? Is it concern that the patients have proprietary rights to their data? What is the issue that's being addressed?

Christina Hyde – OCR
If you're talking about, again, the distinction between when consent would be required versus not downstream I think the concern is that the researcher when they get the initial research consent from the individual has made a promise to the individual to only use their data for certain research purposes and that downstream use of that data for research purposes should be consistent with that promise. Joy, do you have anything to add?

Joy Pritts – ONC – Chief Privacy Officer
No, I think that's same to say given the ANPRM.

Christina Hyde – OCR
Right, I mean this is all subject to comment. It's putting it out there for—

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
It's just helpful to know what is the lever or the concern.

Linda Koontz – MITRE – Principal Information Systems Engineer, Privacy
Well, there's also, I believe, language in the ANPRM that addresses the other issue, I think, that you raised, Wes, which is that the nature of de-identification may evolve over time.

Judy Faulkner – Epic Systems – Founder
My question is if the rule is that it has to be for the purpose that it was originally said won't almost every agreement after that say, "We may use it for other things as well," and let the patient sign it then? Won't they change the way the patient signs it?

Paul Egerman – Software Entrepreneur
Well, we would have to approve that consent form and I'm not sure our IRB would approve the consent form that is for anything.

M
Well, I think one would have to ask the question how would IRBs—I mean it's extraordinarily difficult to recontact patients that you don't currently have contact with to get permission to use their data, so if IRBs are currently working under the assumption that de-identification is a way to avoid that difficulty might

they not relax their concern for reuse of un-identified non-specific identification of the use of data given that they'll … just got a lot harder. I hope that made sense.

Christina Hyde – OCR
The consent pieces of the ANPRM do describe bringing in a standard brief general consent form that would allow the individual or provide for the individual to agree to broad future uses and that would be obtained—the thought is at the time that the original research was done or at the time of the original collection of the data or specimen it's in the clinical context. There is some discussion about whether there should be handfuls of special categories of research that the individual can say no to. I think some of the examples are creating a cell line or reproductive research, so whether there are specific categories that the individual can say no to but still agree, generally, to the future use of their data or they could say no. They could say no altogether.

Paul Egerman – Software Entrepreneur
So just a couple of questions, Christina; one, I'm a little confused, is patient consent required or proposed to be required for the use of de-identified data?

Christina Hyde – OCR
It depends on whether the data was originally collected for a non-research purpose or a research purpose.

Paul Egerman – Software Entrepreneur
It's for non-research. In other words, suppose we sort of—most of us on this phone live in the treatment world and so I'm confused, for data that is collected to treat patients is the data is de-identified is patient consent still required for it to be used for research?

Christina Hyde – OCR
No.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
I want to raise the question about is it possible to ever state in this electronic health record world of the future that we're working so hard to achieve that you're not collecting data for research purposes, and what I mean by that is if you look at any of the justifications for the stimulus spending and for the deployment of EHRs of course one is better patient care and better quality but another is to facilitate research, and I think there's an implicit assumption in the effort that we go to collect very carefully structured and properly identified and nomenclature mapped etcetera that that's to benefit research. I wonder how you can ever say that you're not collecting data with the potential for research. I mean I guess there's a legal way to say it probably retroflected in the consent statement but in a way we're hoping to create all of this data for research.

Paul Egerman – Software Entrepreneur
I just want to make sure what we're doing right now though is understanding the Common Rule, the applicable provisions of HIPPA and what the ANPRM says, and so that's, I think, more questions about what does the ANPRM say and how does that work with the Common Rule and HIPPA.

Gayle Harrell – Florida – House of Representatives
I do have another question, we've kind of focused in on consent, how does the Common Rule work on the security side of things? We've talked more about the privacy consent issue but where does it all fall in security?

Christina Hyde – OCR
There is a great chart in the ANPRM and I don't know if everyone has it in front of them—the ANPRM—it's on page 44527 but it brings together what is being contemplated in terms of the rules for consent for the standardized data protection, for registration with the research office and prior review by and IRB, and based on how identifiable the information is, and so I would just ask that you all take a look at that. I think it sort of brings it all into one picture but to answer the questions in terms of the standardized data

protection the ANPRM contemplates that there are informational risks with respect to the use of data for research purposes. The standardized data protection under the ANPRM would vary depending on how identifiable the data is. For de-identification while you wouldn't need to apply security rules like protection there would be a prohibition on re-identification. For identifiable information there are questions posed and it's being contemplated that there would be some standardized data protection modeled on the HIPPA rule, including breach notification that would apply to that information.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
In a nutshell what I'm hearing, having not read through the ANPRM yet, it sounds like they're increasing transparency as well as the need for consent but in balance to that it sounds like they're also making it easier to get consent. Is that your impression having read it?

Paul Egerman – Software Entrepreneur
Who were you asking, Dixie?

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Anybody that's read it, Joy—

Joy Pritts – ONC – Chief Privacy Officer
We have a—because that is a ANPRM we're kind of limited to talking about what's exactly in it as opposed to giving our impressions but I think that there is language in it that says the intent is to simplify the consent process because right now even for information it's quite lengthy forms and difficult for individuals to understand what they are saying.

Richard Platt – Harvard Medical School – Professor & Chair
Does the notice address the issue of people who don't receive care and therefore the usual ways of obtaining consent really don't apply but lots of important research depends on being able to understand the health status and care delivered to entire populations, and so if people who are eligible for care don't ever present for care that's important information and I don't hear anything in the discussion we've had so far that would allow for obtaining consent from those people in a meaningful way.

Paul Egerman – Software Entrepreneur
That's an interesting question, Rich, but our focus is going to be on ONC programs and privacy and security so we'll mainly be focusing on people who are presented for care.

Richard Platt – Harvard Medical School – Professor & Chair
Okay if that's really the …admit I to heard the notion that—I mean if I had an electronic health record but its empty is that outside our focus?

Paul Egerman – Software Entrepreneur
Say again please.

Richard Platt – Harvard Medical School – Professor & Chair
If my EHR is empty because I never received care, I never presented for care, and therefore couldn't give consent is that situation, that population of people who are really very important, is that outside of our scope? If it is I won't bring it up again.

Paul Egerman – Software Entrepreneur
I don't know the answer. It's a hard question because we don't normally think of someone who has never had treatment as having an empty record. We think of them as not having a record. I would guess that another way of stating the question would be is it permissible to inquire whether a patient has a record without the patient's permission that they would have not given when they didn't show up to not have treatment and that's an interesting question. I think it might be worth some discussion.

Richard Platt – Harvard Medical School – Professor & Chair

Well, a broader way to put it is most health plans are covered entities and so I assume that most of this discussion applies but they have lots of people on their books who are effectively ghosts, and with the use of electronic information that they hold about those people to the EHRs or not it seems to be—

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It's designated record sets.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

I would say there—so you're saying they never gave consent because literally they got assigned by their employer and they haven't ever had interaction with the health plan?

Richard Platt – Harvard Medical School – Professor & Chair
Yes, for instance or their employer or a state Medicaid agency or there's 15,000—this is not a random sample of people so if they're systematically excluded because of these consent provisions it will have a powerful effect on results and interpretability and—

David McCallie – Cerner Corporation – Vice President of Medical Informatics
I think that's—I would say the issue for us is the degree to which health plans are covered by ONC programs and in general health plans are covered by NCVCH, I think.

Paul Egerman – Software Entrepreneur
It's an interesting question. I wrote it down and we'll try to, perhaps, return to it later. It might be broader than health plans is you sort of like fast-forward ourselves through the Affordable Care Act in theory there will be a time when every American is covered by insurance and you could have every person assigned to like an accountable care organization so there could be some structures where that's important. I'll put it on the list; although, I think we have a few other issues on the list ahead of that.

Let me get back to my question. I want to start talking a little bit about previous tiger team recommendations. Do we have other question though about the ANPRM, the Common Rule or the relevant aspects of HIPPA?

Judy Faulkner – Epic Systems – Founder
The only question I have is to comment on what David brought up a little bit earlier and that is I just think we're going to see more and more movement towards the EMR as the research tool especially as we get more into practice based evidence instead of necessarily evidenced based medicine through clinical trials, and then will we be in a situation where the things we decide here will retrospectively become attached to the electronic health record because of the evolution of how it will work with research. Is that what you were worried about to, David?

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Yes, Judy, that's well said. I think that phrase practice based evidence. The notion is that by capturing information in sufficient structure so that it can be analyzed for questions that we don't yet know are important questions we are effectively simply preserving the ability to do research on any number of things even though the data wasn't collected for that expressed purpose.

Judy Faulkner – Epic Systems – Founder
Or it may be too but what I'm hearing from the IOM and other places is that there's less than 10% evidenced based medicine available for appropriate decision support, and the way we're going to test that is from practice-based evidence. I do think we have to keep in mind how this may end up affecting the electronic health records.

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
Can I ask sort of a separate question but I think it's relevant, is this ANPRM discussion registry is it all the role of the registries and repositories?

Christina Hyde – OCR
I mean it certainly discusses repositories because there's a big focus on the ability to use biospecimens for future uses. How specific it is to registries I'm not quite remembering at this time but much of this is prompted by the fact that the use of existing data and specimen is important for research purposes.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
One more ANPRM question, there are several points where you mentioned bringing things into alignment with HIPPA on the definition of de-identified data, is there any mention in the rule or in the ANPRM about changing the definition of de-identified data or is it sort of an assumption that HIPPA is the current gold standard for that?

Christina Hyde – OCR
There is a question or two in the ANPRM about whether it's appropriate and what folks think about bringing in the definitions of what's identifiable and not under HIPPA into this construct but also in a more uniform manner but also whether the definition of de-identified information under the Privacy Rule is sufficient or should be reviewed periodically given advances in technology etcetera.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Okay so it does open the door for that to be discussed, okay. I mean I'll just register this. I don't think we should go deep on it but I think that the understanding about re-identification of data has advanced dramatically since the original HIPPA rules were written. I'm not sure I want us to revisit that though.

Paul Egerman – Software Entrepreneur
It's a hard one.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
It is. I mean you look at a tissue bank no matter how much de-identification you put on the process to collect those tissues if it's got DNA in there it's identifiable, right. I mean there's a reduction adum sertum to some of this but I hope we don't have to go and massively revisit that.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Paul, what is our intent? Are we as a tiger team going to submit comments or is this FYI or what?

Paul Egerman – Software Entrepreneur
Great question, the answer is yes we're going to submit comments. That is assuming we can come to a consensus about what we want to comment on but the comments are due, according to the ANPRM, September 26th and our intent would be to, as a group, go through this and make comments in areas that impact ONC and impact privacy and security. Those comments could come in the form of responding to some of the questions in the ANPRM or it could be just our own comments on various issues, and I'm actually going to go through a series of questions that Devon put together as to places where we might choose to make comments.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Technically we're recommending comments to the HIT Policy Group, is that right?

Paul Egerman – Software Entrepreneur
That's correct. I appreciate your making that statement, Wes. Technically the way it works is our tiger team doesn't really make comments. We would prepare a comment document that would need to be approved by the HIT Policy Committee and that would be the group that would make the comments and submit the comments and respond to the ANPRM.

Gayle Harrell – Florida – House of Representatives
Paul, and those comments would be relative only to things that are specifically addressed through the … of ONC?

Paul Egerman – Software Entrepreneur

The answer is yes, that would just make sense for us to do that. The doesn't preclude any individual on this call from making its own independent comments for yourself or for your organization but that would seem to be the prudent thing for us to focus on, is ONC and privacy and security.

Okay, I'm assuming the pause means there are no more questions. What I want to do is—

Judy Faulkner – Epic Systems – Founder
Can I ask one, Paul? You may have done this in the beginning, maybe I missed it, I'm not sure I did. Who on the line is researcher? I don't mean works with researchers I mean is a researcher?

Paul Egerman – Software Entrepreneur
I believe Richard Platt.

Judy Faulkner – Epic Systems – Founder
Are you the only one, Richard?

Richard Platt – Harvard Medical School – Professor & Chair
Yes I'm …

Paul Egerman – Software Entrepreneur
We're trying to recruit a few other people. I think as you can tell from the call there's a number of people who appear to have experience with this but—

Neil Calman – Institute for Family Health – President & Cofounder
Our organization also does a lot of research using EHR data both internal researchers and also people externally coming in to do research in our organization.

Richard Platt – Harvard Medical School – Professor & Chair
To the extent that it's relevant I share the IONs CDR innovation … and that … is probably going to enlist … as a collaborative with the proposed …

Paul Egerman – Software Entrepreneur
That's great. That's probably a very different perspective or broader perspective.

Richard Platt – Harvard Medical School – Professor & Chair
Right, they're making no overlap at all in terms of …

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Just in response to Judy's question—which I'm sure is true of probably most of us—I do research on de-identified data. I mean technically, I guess, maybe that might not be called research under some of these definitions but I'm very much interested in implication of what might change about the use of de-identified data.

Paul Egerman – Software Entrepreneur
So let me move this discussion along. What we wanted to do is very briefly remind people of various tiger team recommendations that we made in the past that also might be helpful to keep in mind when we discuss these issues and in doing that the first bullet you see on your screen is important. When we made our previous recommendations we were really focused on exchange of information for Stage one of meaningful use, so we made these comments sort of like in different—thinking about a somewhat different world as it were, and we established these three core values that might be important.

The first one is patients should not be surprised to learn what happens to their health information. That might be an interesting core value to think about relative, for example, to your comment David that everybody expects data to be used for research. The question is do patients necessarily expect that? Is there some transparency issue here? The second core value is that the provider/patient relationship is the foundation for trust and health information exchange. The third core value is we said that as key

agents of trust for patients providers are responsible for maintaining the privacy and security of the patient's records, but then we add a parenthetical comment that they can delegate certain responsibilities to others but must do so in a way that maintains that trust.

Essentially, if you look at those core values in the context of this past discussion about research these things that we said was we said all entities involved in health information exchange should follow the full complement of fair information practices, and these practices have to include openness and transparency and include collection, use and disclosures limitation, which is only what is necessary to accomplish a given purpose and they have to have reasonable security safe guards, so that's also a concept that we might want to think about and ask how that applies to this research ANRPM. Then we made some comments about consent, and I don't think … included this in her presentation. As I read the ANPRM—I may have gotten this wrong, maybe something I read that was tangential to the ANPRM—that there is some questions about the consent documents themselves. That they're many pages long and whether or not they make sense to patients but what we said about consent was it's not required for directed exchange but when the decision to disclose or exchange information is not in control of the provider or the provider's organized healthcare arrangement, an OHCA, patients should have the right to exercise meaningful consent to their participation, and then relative to what we meant by meaningful consent we listed a series of bullets, which is advanced time to make the decision, not compelled, full transparency and education, commensurate with the circumstances, consistent with patient expectations for privacy, and also it must be revocable. That's what we said as it relates to the information exchange, and it's important to keep these in mind to think about how do they apply to this research situation.

Based on those recommendations, there is a series of slides that Devon put together and these are areas where it's possible that we might want, as a tiger team, to weigh into this entire process. I'm going to do my best to walk you through this but since Devon wrote it I may not get this right so please speak up if you think what it says here is better than what I'm saying. The first one is the scope of the rules, what constitutes research. This speaks a little bit to your question, Judy, about the difference between research and quality. What's written here is further clarification needed on the distinction between the definition of research and the definition of operations? With this scenario do you think it is appropriate for us to comment on or that we want to weigh in on? What do people think?

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
I think we should weigh in on that one because I think that some of the functions that we expect our systems to do and that are good for them to do I think we need to make sure those are not included in the definition of research, like learning systems. We would like our EHRs to become smarter over time and make better suggestions, the whole clinical support evolving over time, so I think it would be appropriate for us to make a statement about that.

Paul Egerman – Software Entrepreneur
It's interesting that you use the word learning because the learning helps us. I mean it's an expression that exists throughout the ONCs strategic plan and Judy Faulkner made the comments about practice based evidence and that is indeed what is happening right now where people are starting to use these quality reports internally and they're saying, "Well, we have this kind of infection rate but maybe if we saw this research and we tilted the bed a little bit the infection rate will go down so we're going to give that a try and see what that does," and so that is sort of a quality aspect. There's a certain operational aspect but there seems like there's a certain research aspect to it to and—

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
I was thinking more in terms of integration decision support because the example that you gave there was more, what I would consider, population kind of management but in a clinical decision support where you're really allowing the system to tweak the rules over time. If we're not careful that might not be included in the definition. I think that would not be productive.

Richard Platt – Harvard Medical School – Professor & Chair
I support this notion of weighing in on what should count as research.

Paul Egerman – Software Entrepreneur
Okay. Next question is what are the privacy and security rules that should govern research? Basically, the bullets say we previously recommended that all entities be accountable for complying with a full complement of fair information practices including the security protections, which is a question that Gayle raised. The question is should the tiger team suggest or require research to address other fair information practices in addition to what's being described about consent?

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
I am not sure I understand how this gets to be in our brief. If you say that someday it is dual purpose—that is clinical for operations, treatment, etcetera and research and some data falls into one or the other category we are already sounding forth on what's necessary for security for anything to involve clinical purpose. Where under ONC's charter do comments on data that's always for research belong, if at all?

Paul Egerman – Software Entrepreneur
I don't know the answer to that. At the risk of being completely wrong I'll throw out an answer though, which is to say that I think what we've done so far really relates to covered entities and information gathered for treatment purposes but if there's information that is held by a researcher, that is not a covered entity. Should that researcher be required to have the same kinds of rules that the covered entities have?

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Maybe it's just a case of who issues those rules. I happen to think from everything I've heard that it would be a pretty imposing mandate on research institutions to bring all of their research systems to the level of security that is described in HIPPA. Maybe they should and maybe they shouldn't, how fast they should and how disruptive to research that's going to be, those are important issues to be discussed. I just don't know that they're in our purview.

Paul Egerman – Software Entrepreneur
So you're saying no we should not address this issue.

Gayle Harrell – Florida – House of Representatives
I would disagree. I think if that is information that gleamed out of these records and if it's identifiable that there needs to be the same kind of awareness and information practices including security if there are breaches, if there are disclosures or whatever.

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
The counter to that though is that, at least to the extent that a patient signs a consent for or authorization for disclosure however that data that is used subsequent to authorization though you're singling out research when any other authorization that a patient was to sign and a disclosure that would occur as a result of that authorization would not have equivalent security as part of the HIPPA Security Rule. And frankly, I would say that the long history of IRB regulated research is one that there's probably fair less likelihood of a breach than in other contexts.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Now, I'm going to argue the other side of it. We have currently various disclosures that we do for consent or not for consent. We can disclose … payment operations. We can disclose to law enforcement. We can—

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
I'm only talking about the ones with consent though. I can give anybody any data—I can sign an authorization to disclose data to anybody today, and once that data is in the person's hands it's in their hands. They can do whatever they want with it.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

So your point is, I guess, whether Gayle's correct, which I'm not disagreeing with Gayle, that someone in the Government should implement a policy that says, "If you get personalized data and it's breached you should be obligated to report it." It's just a question of whether we should do that.

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
Well, my point is simply that we're ultimately holding research to a higher standard than either individuals or groups that might receive data pursuant to an authorization.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
No, under the new proposed HIPPA rule anything that's a business associate is held to the same standard.

Paul Egerman – Software Entrepreneur
Our previous recommendation said all entities involved in health information exchange.

M
But I was talking about authorized release, … release.

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
If I go to my next door neighbor and I say—well, my next door neighbor could sign an authorization giving me the right to get his or her information and as long as I have that authorization and I go get that information I could do whatever I want with it.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
As can any personal health record that you send your information to.

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
My only point here is that if a research study gets an authorization from a patient to receive data how is that any different than the example that I described?

Gayle Harrell – Florida – House of Representatives
You have the situation potentially where the information is available because it already exists. It comes down to that original question, is this exempt information? If its exempt information and you don't need consent then there comes liability with it.

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
Well, I'm not talking about information that doesn't require consent. I was speaking of this situation where the far majority of research data gets released pursuant to an authorization in my experience.

Gayle Harrell – Florida – House of Representatives
If your data mining large amounts of EHRs I'm not sure that there's a consent element in there.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
And that's pure context. If it's identifiable then it would require a waiver from the IRB.

Paul Egerman – Software Entrepreneur
Let me put a different perspective on this discussion, which is to remind everybody of the concept that patients should not be surprised and when you look at the concept that patients cannot be surprised when they find out what happens to their data it also occurs to me that most patients do not know what a covered entity is. They would just sort of take a guess that their signing some consent form or whatever that—especially if their physician hands it to them and says, "I'm participating in this interesting research study that's being done by this great organization and gives the name of some non-profit organization, do you want to participate?" It seems to me the patient's expectation was that their data was being handled the same way the physician handled it.

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security

The bust to that though is that the IRB, as part of the IRB process, would approve a form of consent that the patient had signed, which describes things like the uses of data, the potential harms, potential risks, all of those types of things. So if the patient reads the consent that is associated with the IRB study they would recognize how that data is going to be used. Now, again, I deal with my IRB all the time so maybe I'm just used to the fact that most data—

Paul Egerman – Software Entrepreneur
The purpose of the discussion should not be to solve this. The purpose of this discussion is to decide is this a question we want to discuss.

Richard Platt – Harvard Medical School – Professor & Chair
And my point is that it's a jurisdictional issue. I mean I believe in what Gayle said. That the principals that we describe of common values, I guess you describe, are that the patient should not be surprised and so forth but what I don't under—you can take a value and you try to implement it reflected in information you get into a bunch of issues about who is regulating whom. I don't know that we should do any more than reflect on whether the appropriate body that governs the handling of research data should apply those standards. I don't think it's—clearly part of the confusion from the patient is that often the organization doing the research is the organization that is treating them and they may not remember five years later that they signed a general consent for reuse of their data five years before. I mean those are important issues but I just don't know that we would be able to comment on them.

Gayle Harrell – Florida – House of Representatives
I'd like to put one more thought in, as Judy said; we're going into a new era of information that has never been available before when you have major segments of society having electronic health records. When you get down to the ability to data mine that information and you get that practice based evidence. The research that could be done with that is at a different level than we've ever had the ability to do before, and I think the risk of what happens to that information if it's identifiable increases geometrically as we move forward. I think we have the ability and we should be commenting on this.

M
… there. I mean I don't think we wiped out the folders.

M
Inaudible

Leslie Francis – NCVHS – Co-Chair
Can I put in two quick points here that I'd like at least some reaction from Christina about? The first is the question of revocability and what is contemplated with respect to withdrawal and revoking consent. That relates, obviously, to one of the basic points consequence we've made. That otherwise is that if we're just focusing on information risks, IRB review would look at whether the researcher was assessing only the information that was needed for the study, public specification and use limitations. If we're focusing on just protecting security I don't know whether you'll get the same review of purpose specification and use limitation so there's a possibility of more data being used in research than might have been used previously.

Christina Hyde – OCR
In terms of the revocation, I think the ANPRM does contemplate revocation of these consents. It doesn't do it in any detail and I think the department would certainly welcome public comment in that area given the operational issues with respect to revocation of consent for future uses when the data is handed downstream to other researchers, and the second issue, I think, was on use limitations and collections, is that correct?

Leslie Francis – NCVHS – Co-Chair
Yes.

Christina Hyde – OCR

The ANPRM is focused mostly on data security and information protection standards not so much on privacy use and disclosure limitation. There is, however, a statement in the data protection section that states that the department is also interested in whether there are other changes that might be made to the Common Rule, such as appropriate limitations on researcher's disclosure of the information that would strengthen and create more uniformity and the promises of confidentiality to human subjects. There is that statement in the ANPRM.

Paul Egerman – Software Entrepreneur
So, Christina, I'm listening to what you just said so it seems like that is in terms of the jurisdictional question that Wes is asking, it seems like that is like the opening that we are being asked if there's something that can be done for greater uniformity.

Christina Hyde – OCR
I don't think that I can comment necessarily on what the department will have jurisdiction on or not in terms of revising the Common Rule until the ANPRM comes out but there's a request for commentary in that area.

Paul Egerman – Software Entrepreneur
Very helpful, I appreciate those comments, Christina. So getting back to this question, the question is—so like the last question you see on the screen—should tiger team suggest requiring researchers to address other fair information practices? I'm not really right now asking us to answer that. I'm asking, do we think that's a fair question that we should be discussing?

W
Absolutely.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Yes, I think what we just heard they're actually asking for.

Paul Egerman – Software Entrepreneur
So we can put this on the list. Now, that doesn't preclude us from deciding—if I'm hearing Wes correctly and possibly John correctly—that we don't want to make any recommendation but at the same time it seems like it would be a fair question to at least ask. Let me move on to the next topic that's listed here by Devon, which is a great topic. Says here, Common Rule does not require consent before information that is not identifiable can be used for further research. Then we have these bullets, Common Rule standards for identifiability are less stringent than HIPPA's de-identification standards; although, ANPRM does propose adopting the HIPPA de-identification standard. Is that a scenario that we can address?

The second area says, "Even with the more stringent standards for indefinability what does the tiger team think of this policy?" In other words, how do you balance researcher and public concerns? Do previous tiger team recommendations on consent help resolve some of these issues? So what do you think about this? Is this a good question for us?

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Absolutely, patients should not be surprised.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
If it's de-identified though there's no way to know whose being surprised.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
However, the de-identification standards are so much lower than HIPPA's standards. I think we absolutely need to weigh in on that.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
The second part though assumes equivalence of standards there.

Paul Egerman – Software Entrepreneur
If I could—this is awkward but I'm doing my best to be like chairman of the tiger team and not necessarily making personal comments. In a lot of these discussions there's a basic assumption that research is good, and I think that's probably correct but we really haven't defined research and maybe some patients might not really think it's really good even for the data for them to be participating, so I think it's an interesting topic for discussion.

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
Can I suggest probably though the one thing that we don't know about and we're not qualified to speak to is what are the requirements of research in terms of different levels of de-identification. I can tell you that when you go to a researcher and say, "Can you use de-identify data?" They'd say absolutely not but then they say what elements I need and they list off two or three fairly benign elements that need to be added in order for them to successfully use the data. I think part of the issue is how do we deal with different levels of de-identification and what are the standards. Right now there are really only two standards. Only if it's partially de-identified as being a data use agreement or you use a fully de-identified data. I think there are other levels of de-identification that researchers will say are important to them.

Richard Platt – Harvard Medical School – Professor & Chair
Paul, I think we have to discuss this. I think we may need to get some expertise on what's … but I think it needs to be on your list.

M
Inaudible.

Paul Egerman – Software Entrepreneur
These are great questions. I mean I don't know about everybody else, I look at some of these question and say, "This is going to be fun." This is really very, very important information and it's not easy because we want the researchers to do their job. We want to protect the patient's privacy. This is good stuff.

The next areas, my only concern is there are a lot of questions here we've got to decide also that ANPRM would allow researchers to have access to the identifiable data and still be able to benefit from not requiring IRB approval of being required to obtain a consent, and this says, "The rational for this is unclear, thoughts? Does that make sense to anybody?

Richard Platt – Harvard Medical School – Professor & Chair
Right now the way HIPPA's designed is if it's proprietary research it would actually, I think, be fairly close to this. I don't know if they're trying to extend that beyond that or what.

W
This is cohort identification. When they go in and see do I actually have enough people with breast cancer in this data to then go to the next step and get the consent to participate.

Paul Egerman – Software Entrepreneur
The next bullet says, "ANPRM is proposing to streamline the process for obtaining consent when it is required. Do we want to weigh in with thoughts on meaningful consent?"

W
Absolutely.

Paul Egerman – Software Entrepreneur
Okay, research using existing data does not require any independent approval. Is that correct?

David McCallie – Cerner Corporation – Vice President of Medical Informatics
That was at point number four.

W

Yes, that is.

Paul Egerman – Software Entrepreneur
Instead researchers are permitted to submit a summary form describing the research and the ANPRM is proposing to audit and monitor such research to ensure it raises low risk.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
At the very least this should be reworded because that's not what it currently—

Linda Koontz – MITRE – Principal Information Systems Engineer, Privacy
Paul, can I try for a clarification on this?

Paul Egerman – Software Entrepreneur
Yes, absolutely, I'd love it.

Linda Koontz – MITRE – Principal Information Systems Engineer, Privacy
Okay, the things I want to clarify that kind of got lost, and I apologize for this, in the structure of the presentation was that yes, the exemption four does involve information that cannot be identified directly or through identifiers. But what the issue on the table in the Advanced Notice of Proposed Rule Making is to expand that category, and what it says—and I'll just read it to you to avoid confusing anybody further—it says, "To expand the current category four exemption, which is regarding the collection or study of existing data documents, records and biospecimens. And it would be expanded to include all secondary research use of identifiable data and biospecimens that have been collected for purposes other than the currently proposed research provided that specified due consent requirements are satisfied."

Leslie Francis – NCVHS – Co-Chair
Can you explain that? I'm not sure I understand the intent.

Linda Koontz – MITRE – Principal Information Systems Engineer, Privacy
I will call on Christina and she can help me with this but my understanding is what they're doing is there's an exemption category here for pre-existing data that they're proposing to expand to include identifiable data, and then as I would personally articulate it, what they're saying is like we're going to have you register with an IRM. You're not subject to IRB review but you're registered with an IRB. You're going to have to follow the consent rules that we previously talked about today, which are new, and you're also going to have to have these new data protection standards for what you're doing and you may be subject to audit. You can see that they're expanding but then also putting additional controls.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
So what I hear you saying is we've defined a new general consent, you can use my data in the future, and we're now defining the operational approach under which you get access, which researchers get access to that data, and it is not IRB preapproval but registration with the IRB. It is certain security standards and it is the potential for an audit. Is that correct?

Linda Koontz – MITRE – Principal Information Systems Engineer, Privacy
I would direct you to the same chart that's in the Advanced Notice of Proposed Rule Making that Christina mentioned, and it is two pages in the notice and it does a really good job of actually summarizing what those requirements would be. Christina, did you have something to add to that?

Christina Hyde – OCR
No, no.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Is there a way to put that up on the PowerPoint right now?

Paul Egerman – Software Entrepreneur
Maybe we can—because we're running out of time. I think what we're going to do is—

M
Inaudible.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
I think we all need to look at that very carefully.

Judy Faulkner – Epic Systems – Founder
As we begin to collect patient reported outcomes where the patients are commenting on did this work or didn't it work and it feeds back into the department, the specialty looking at it, to say should we still do A or should we do B, which is better, so that when we trigger decision support we do better with our patients. Is it going to be delays in being able to get this done so that instead of finding things quickly and being able to adjust more quickly so that you preserve the health of the ones coming up next in getting the same treatments I think we have to look at not just what's the right thing to do but the time lapse on these—

Paul Egerman – Software Entrepreneur
… Judy, also in my mind, relates to what's the definition of research.

Judy Faulkner – Epic Systems – Founder
Yes, right.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Yes, very fundamental, Paul.

Paul Egerman – Software Entrepreneur
That's a key issue. There's a key issue here also in this sentence that says, "There are no specific provisions regarding transparency to the public about research." It seems to me transparency is good. There's not really a good argument against transparency and, in fact, transparency might be good for the research institution. If people know that somebody's doing research on something they might say, "Well, I want to help out. I want to go to that doctor or go to that place because it seems like that's the nice thing to do. I'd like to help." It actually could increase the activity through greater transparency. I think this is an area for us to focus on. I'm sort of rushing a little bit because I also want to make sure I—and we're getting close to the end and I want to make sure we have time for public comment.

M
This is a definite yes.

Paul Egerman – Software Entrepreneur
Okay and then this is the, next slide, issue that we talked a little bit before, ANPRM proposed researchers adopt baseline security measures similar to what is in the HIPPA security rule. This is sort of like do we want to say yes? Do we support that rule? Do we want stronger protections so that seems like that would also be something that we would likely make a comment on and I think that is the last question. Yes, that was the last question, so let me just ask are there other questions that weren't on this list that you think are important for us to address?

Gayle Harrell – Florida – House of Representatives
I think that the whole definition of what is research needs an in depth conversation.

Paul Egerman – Software Entrepreneur
I think that's on the list but that's definitely—

David McCallie – Cerner Corporation – Vice President of Medical Informatics
I think it's also on our list but just going back we talked about meaningful consent, maybe we have a footnote to add around the research implications that this change in rule would add to that—

Paul Egerman – Software Entrepreneur
Yes, I think that's a great comment. I think what's happened with a lot of the informed consent stuff is they protect the provider or the research firm more than they inform the patient and help the patient, and so we would—it could be an area we want to address.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
I agree with you, Paul, and I would like to add to that we should look at this to see whether we think they've obtained the optimal balance between a requirement for consent and transparency because in many cases what would be best for the patient is really to be able to know that something's happening not necessarily have to give them yet another piece of paper to sign.

Paul Egerman – Software Entrepreneur
Okay any other suggestions/questions?

Neil Calman – Institute for Family Health – President & Cofounder
I apologize if somebody mentioned this; our system went down about an hour ago so I've been trying to deal with that, technology. You know how we've been talking on the Privacy and Security Tiger Team about sort of, I guess, warnings for patients when they download and view their own information and it occurs to me in this environment while providers are becoming well informed about how to deal with this stuff researchers really—it's not part of their normal, I guess, scope to sort of think through, I think, some of these new issues related to what's happening when they're doing research and accessing records either through an electronic health record or printing reports that they're going to later use and other things like that. And just as a general issue just want us to sort of raise whether there's not something there about researcher directed information that needs to be done that helps to improve their understanding of this sort of new world that we're in because that's not a world that they live in all the time.

Leslie Francis – NCVHS – Co-Chair
I couldn't agree with you more.

Paul Egerman – Software Entrepreneur
That's great. It's a fascinating comment.

Neil Calman – Institute for Family Health – President & Cofounder
I don't know how to incorporate that but I think there needs to be some directed stuff, and this has come up recently here where researchers are coming in but they're printing copies of things like that, which people don't really understand that they're now entering into an insecure environment from what was previously a secure environment, and we need to think about how we're going to either teach that or I don't know if that actually is appropriate for this discussion but—

Paul Egerman – Software Entrepreneur
Yes, they may be trained to think of their responsibility to patients just like the patient safety issue, which they may not understand that privacy and security are crucial patient issues made out of, what I call, patient safety issues but it's a different mindset so excellent comment.

So the challenge we're going to have is to get through all of this in two or maybe three meetings in order to meet the September 26th deadline, and go through all the process of getting the Policy Committee to approve what we've written up because this is also going to be a fascinating discussion at the Policy Committee meeting. What we will probably be doing is asking our friends at the Miter Corporation to start to draw up some sort of like positions that we can consider and some materials on some of these questions but what I'd also like to ask the members of the tiger team to do is—if I've got it right our next meeting is on Thursday, August 25th, so we've got almost three weeks between today and our next meeting—if there's a question that you have a strong opinion on here would be to formulate your own view of what we should do on that issue, and through email circulate to the other tiger team members in advance because it would be nice to get a little bit of advanced thoughts and work on these various questions.

Before I start thanking everybody, does anybody have any other comments about the way we're approaching this issue?

Richard Platt – Harvard Medical School – Professor & Chair
That plan sounds great. Will we get a list of the questions that—?

Paul Egerman – Software Entrepreneur
Yes, I will send out a list or we're sending out a list. That's a great suggestion. Let me say special thanks to Linda Koontz, did a terrific job on your presentation. Christina your presence was awesome. Richard Platt, really appreciate to have you part of the group, and Joy, of course, your terrific, and everybody I really appreciate your efforts on a Friday in August, and, of course, Judy Sparrow who has to put up with us day in and day out. So, Judy, why don't we see if we have members of the public who would like to make any comments?

Judy Sparrow – Office of the National Coordinator – Executive Director
Operator, can you check and see if we do have comments?

Operator
We do have a public comment.

Judy Sparrow – Office of the National Coordinator – Executive Director
Okay, if you could please identify yourself.

Carol Bedford
This is Carol Bedford at the American Nurses Association. I don't envy the task before you with all the questions and significant conversation you had today but I would invite you to be sure to consult with the National Committee on Vital Health Statistics workgroup in relation to some of the testimony they may have done in the past. It might inform your thinking conversation in relation to the privacy and confidentiality stuff.

Judy Sparrow – Office of the National Coordinator – Executive Director
Great, thank you very much, Carol. Do we have anyone else?

Operator
You have no further comments.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you.

Paul Egerman – Software Entrepreneur
Great. Well, thank you very much, Carol. Thank you very much to Judy at ONC and the members of the tiger team and enjoy your weekend. Take care.