Cyberseminar Transcript

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Session: Waivers: Common Rule, Privacy Rule, and FDA Regulations

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**Soundia:** Good afternoon everyone. Thank you so much for joining us for our July monthly scheduled training on topics related to human subjects protection and research. My name is Soundia Duche. I’m a program analyst here in PRIDE, the Program for Research, Integrity, Development, and Education, and I’m really happy to be presenting this topic. This is a topic that we’ve wanted to do for a long time. It’s going to be a lot of information that we’re going to be conveying so I’m sure we are going to take the whole one hour and 45 minutes. But as always we’re going to leave time at the end for questions. We found that about 15 to 20 minutes is about what we need and so that’s what we’re going to be working towards today. Today assisting me with the presentation are my colleagues Lucinda Shouse who is a program analyst, as well, in the Department of Clinical Science Research and Development. We’ve been working together, golly Lucinda since a long time, 2011 or so. Also with me today is Dr. Karen Jeans whose the associate director for Regulatory Affairs for CSR&D and Dr. Petrice Longenecker, who is a senior regulatory affair’s officer here in PRIDE as well. Also we are joined today by Kimberly Murphy who works in the VHA privacy office and is also the alternate privacy officer for the VA Central IRB. So we’re very happy to have you, Kim. She’s going to be helping answer any questions related to authorizations and waivers and alterations to HIPAA waivers and anything else that she feels really she wants to chime on. Kim, do you want to say anything?

**Kimberly:** Well thank you for having me on the call. I appreciate it and I’m hoping that we can clarify some of the mystique that’s around the actual HIPAA waiver and authorization process.

**Soundia:** Excellent. Thank you, Kim. All right. Heidi’s already mentioned how to get the handouts. We’ve sent out the handouts, the HSR&D Cyberseminar portal sent it out automatically to everyone who was registered for the training. I also sent out the handouts to the various distribution lists that we use to announce the training and here’s the tinyurl again. If you have any problems, as always, just let Heidi know through the chat feature and she will make sure you have the handouts.

As I mentioned, we have a lot of information to cover today but I think it’s really going to be good. What I did, because there’s so much content, I’ve kind of divided up the training into three segments. So the first segment is really going to be focusing on kind of establishing, setting the stage, establishing the framework for waivers. We’re going to have to first talk about informed consent, documentation of informed consent, and HIPAA authorizations. This is going to be just an overview. We want to make sure that everybody’s on the same page because we know we have people who are new to conducting research as well as overseeing research and those who’ve been doing this for 20+ years. But we’re going to spend a little time kind of setting the stage and covering the basis of regulations that govern informed consent and HIPAA. Then we’re going to go into the meat of our presentation which are waivers. We’re going to be talking about HIPAA waivers and alterations. Waiver or alterations of informed consent. We’re going to be talking about FDA exceptions to informed consent and then waivers of documentation of consent. The majority of our training will be focused on the current regulatory requirements in the Common Rule. That said, we are also going to touch on any revisions expected as it pertains to waivers that we’ll be expected to implement effective, I think it’s January 21st, 2019. So we’ve got you covered on that end too. And then lastly, we’re going to round out today’s training with case studies. We have some really good cases. Because of the way we’re doing the case studies today it’s very important that you do have the copy of the handouts available to you. Many of you have asked and have noted in the various surveys that you complete at the end of the training, you know, when we’re doing the case studies can you please keep the scenario displayed when we’re answering the question. Unfortunately that is just not possible. In order to enable the polling function, I’m not able to show my screen. I have to give up my screen and then Heidi brings up the poll so we will not be able to show the scenario as you’re answering the question. That’s why it’s important that you do have the handouts available, particularly in today’s training where, while we have three cases, we have multiple cases on each case. So you’ll need to be able to go back to the scenario because I won’t be able to go back and forth as often as you would like me to, if at all.

All right. Okay so let's get started. We’re going to begin with kind of an overview on informed consent and HIPAA.

So I love the term full disclosure. I don’t know if anyone else uses it but I use it and the reason I love it so much is when we’re dealing with issues related to enrolling a subject in human subjects research here at the VA we have to think more broadly than just informed consent. We are a covered entity, therefore, we are subject to the Privacy Rule. So in everything we do, when it comes to enrolling a subject and involving and engaging subjects in research, we have to look at it from the vantage point of both meeting the Common Rule requirement as well as any Privacy Rule requirements and so full disclosure, in my mind, kind of brings it all together and says what all do I need to ensure I’m covering, to make sure that I can engage this subject in research, involve this subject in a research activity here at VA, okay? So adequately informing subjects about what their participation in a research study involves relying on both the Common Rule, as well as FDA regulations if it’s an FDA regulated study, and the Privacy Rule requirement for HIPAA. Now both the Common Rule and FDA regulations require that informed consent be sought and appropriately documented from each prospective subject, or the subject’s legally authorized representative, unless the IRB waives that. And in FDA regulations they have a couple of scenarios, a couple of unique situations where they coin it exception to informed consent, where consent is not required. But short of those two situations, informed consent is expected based on FDA regulations or the IRB approves a waiver of informed consent, you must get the informed consent of the subject prior to enrolling them, engaging them in a research study. The Privacy Rule, on the other hand, describes when a written authorization is required before the use or disclosure of healthcare information that is not for permissible purposes as well as it specifies any exceptions allowed to the regulations. So essentially, the Privacy Rule is looking from the standpoint of for an individual, the individual must agree to the use and disclosure of their information, their protected health information, unless it’s for treatment, payment, or healthcare operations or, unless it’s specified in the regulations that they do not have to authorize it. And so we have some, you know, there’s some specific requirements there that we’re going to be talking about as well.

So I added this slide. I know you guys don’t have it in your handout but this is a slide that we’ve used before in previous PRIDE presentations and it’s a slide I stole years ago. I think I found it. Somebody had it at PRIM&R and I loved it so much I recreated it. But what this is, is it’s really kind of merging the Belmont Principles with the Common Rule approval criteria. And we’re going to focus on the upper left hand quadrant, Respect for Person. Because the Belmont Principle summarizes the ethical principles and guidelines for research involving human subjects. There are three principles; respect for persons, justice, and beneficence. So in the context of this lecture, where we’re talking about informed consent, the informed consent process is linked to the principle of respect for persons in the Belmont report. And what that principle states is that you must treat individuals as autonomous agents and protect those with diminished capacities. In treating individuals as autonomous agents, one needs to provide individuals with sufficient information so that they can decide if they wish to participate in a research study. You need to provide that information fully, clearly, in a language they understand. You need to do so without any coercion or undue influence. And you need to make sure that they are aware that alternatives exists. Essentially you need to arm them with all the information they need to be able to decide that they want to participate in that study or not.

What needs to be conveyed to the subject as part of informed consent? There’s certain required elements that have to be covered and conveyed to the individual as part of the informed consent process unless the consent process is waived by the IRB or the IRB approves certain alterations. Here at VA remember we’re both subject to the Common Rule and the Privacy Rule. So they’re kind of, they’re, well with informed consent, there’re three tiers of things we have to look at. One, we have to meet the Common Rule requirements for informed consent. I am not going to go over the specifics here. Kristina Borror is going to be conducting a lecture tomorrow on informed consent and I’m sure she’s going to cover it in her overview there. But the Common Rule has eight basic elements described in 38 CFR 16.116a and six additional elements also described in that section. And I think for the six additional elements there may be one or two where you only have to include them as applicable. But really, for the point we’re trying to make is that you have to meet the Common Rule requirements for informed consent unless the IRB waives it. That information has to be conveyed to the subject. In addition to the Common Rule requirements, if one is conducting FDA regulated research, there’s some additional requirements that you have to meet. Now luckily, the FDA requirements for informed consent mirror the Common Rule requirements for informed consent for the most part. The one additional thing that you’ll find in the FDA requirements is that there is a statement that has to be provided to subjects that are being, for studies where you’re looking at a clinical trial. So for FDA regulated research that involves clinical trials, you must provide subjects with the following statement and it has to be verbatim. That the description of this clinical trial will be available on [www.clinicaltrials.gov](http://www.clinicaltrials.gov) as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results and you can search this website at any time. So for FDA regulated research, we also have to make sure we meet that requirement.

And then the third tier that we have to meet is VA specific elements and there aren’t that many of them anymore. We only have four. With the revision of 1200.05 back in 2014 we reduced the required elements to these four: you must provide subjects with information on any payments that the subject is to receive for participating in the study; information on any real or apparent conflict of interest by investigators where the research will be performed; a statement that VA will provide treatment for research related injury in accordance with applicable federal regulations; and then, as appropriate, a statement that informs VA research subjects that they or their insurance will not be charged for any costs related to the research. So when you’re thinking about the informed consent process, all of this information has to be conveyed to the subject unless the IRB approves a waiver of consent or an alteration. There’s one additional item, I’m not going to call it an element because we kind of associate element with the Common Rule element. But if as part of the research study you’re going to be taking any photos, you’re going to be doing video or audio recordings as part of the research study, that information also has to be conveyed to the subject, prospective subject, and the IRB cannot waive that requirement. You have to convey that information to the subject if you’re going to be taking photos, obtaining photos for research purposes, or video and audio recording. Now just very quickly, just want to reiterate, you don’t have to use the VA form 10-3203 anymore for research, you can if you want, but it’s not a requirement. Typically you want to include this information in the consent form. As I stated, the IRB can’t waive that requirement. So in instances where the IRB waives documentation of informed consent, if you don’t understand that terminology, don’t worry we’re going to get to that, but if the IRB does waive documentation of consent, you still have to get the subject’s permission to be able to record the recording and there’s a process. You can talk to your privacy officer about that but it goes something like this. You’re on the phone or you’re in person with the prospective subject, you tell them, hey we’re doing this study but we’re going to be audio recording it or video recording it. Do I have your permission to start the recording? The subject says yes. You then start the recording and you repeat again, my name is so and so, you’re participating in this research study, whatever the script is that the IRB approves, do you agree to this recording? And the subject says yes again. So it’s not on the slide, I realize that, but just wanted to make sure I mention that. Keep this in mind and if you need to talk to your privacy officer about this, or your IRB, please do so because it’s very important.

Documentation of informed consent. How is that done? When is that required? Essentially, unless the IRB approves a waiver of consent, then regulations require that you obtain written consent, documented consent, unless the IRB approves a waiver of documentation of consent. We’re going to talk all about all of these waivers. But here at the VA, if you’re conducting VA approved research, you must document that consent using a VA template. It doesn’t have to be the VA 10-1086. You can use that, that’s fine, many facilities do use that. The VA central IRB continues to use that, and there’s no problem with that, but it has to be some form that’s recognized by your local facility as a VA form or VA template. When I say form, I don’t mean an official VA, you know, form that’s numbered, but it cannot be your affiliate informed consent template, for example. Veterans need to know whose responsible for the research and if it’s a VA approved study using a form that clearly indicates this is a VA study on this form helps convey that information. What else has to be on that form? Our requirements are that the IRB approval date must be documented on the informed consent form that’s approved by the IRB. Does it have to be on each and every page? Not necessarily, but it does have to be on the form. Do I have to include the expiration date on the consent form template? No you do not. If you want to, you can. My honest opinion and recommendation is don’t. You just end up, I think, increasing administrative burden because all of a sudden then the form expires, you have to, you’re forced to, provide the form and put a new form out even if there may not be any changes. So if you’re doing that, you’re not wrong, it’s not that you’re doing anything incorrectly, but you may want to revisit that because you may just be adding to your workload unnecessarily, and potentially increasing compliance issues unnecessarily. Lastly here at the VA, for VA approved research, the informed consent form must be signed and dated by both the subject, or the subjects legally authorized representative. And the legally authorized representative comes into play when you’re dealing with a subject who has capacity issues, diminished capacity, those types of things. So by the subject or the subjects legally authorized representative as well as the person obtaining informed consent. So two people, unless the IRB specifically waives the requirement that the person obtaining informed consent signs that form. And we’ll talk a little bit later about the scenario in which that might be something you want to consider.

Now remember we’re a covered entity so we have to always consider the Privacy Rule and HIPAA protections for our protected health information. And this is where I’m so happy we have Kim on the call because she’s going to chime in on this one. But essentially, the Privacy Rule states that except as otherwise permitted or required by the regulations, a covered entity may not use or disclose protected health information without a valid authorization. So except in cases where the regulations fully state you don’t need an authorization, you must get the subject’s written permission when you’re using or disclosing PHI for purposes that aren’t covered under HIPAA. So what is PHI? PHI is defined as individually identifiable health information that’s transmitted or maintained in any form or medium by a covered entity. As we said numerous times, we’re a covered entity. Any information that contains individually identifiable health information that we receive, that we store, that’s in paper format, if it’s any electronic format would be considered PHI. So this obviously begs the question, well what is individually identifiable health information? And I’m going to ask Kim to kind of chime in here because there are some very, very subtle nuances with the definition being used for individually identifiable health information and so she’s going to talk about the definition and talk about how this plays out. Kim, can I turn this part over to you?

**Kimberly:** Sure and I’m hoping to make it as simplistic as possible. There was a policy decision made which basically indicated that all Veteran information, even something such as demographic information, any Veteran information collected and stored within one of our system of records, including the research system of records, is considered protected health information. So there was a nuance difference but in the sense where we’re actually utilizing Veteran data, there isn’t a difference. It’s all protected health information.

**Soundia:** Excellent. Thank you. That’s very helpful. Now what about, Kim, cases where we are enrolling caregivers or providers? Does this still stand? Does this hold? For caregivers and providers when we’re asking them questions maybe where we’re not collecting any health information. Would HIPAA still apply?

**Kimberly:** If we’re not collecting any health information on providers, HIPAA is not triggered. So you don’t have to worry about a HIPAA waiver or HIPAA authorization. But it depends on what we’re doing with the caregivers. Because quite frequently we may be asking questions about like their stress level and reference to being a provider and what not so it depends on the type of information that’s being collected for the caregivers. But in the same time, I have seen some protocols where they’re actually taking blood samples from providers. So something to that effect would actually trigger HIPAA, and that is a consideration when you’re actually reviewing the protocol, and it basically depends on the information being collected under the purview of the protocol.

**Soundia:** Thank you. Very helpful. So individually identifiable. What does that mean? Because we’re a covered entity, because we’re a signatory to the Common Rule, we have to take into consideration both definitions of identifiable. The Common Rule gives a lot more flexibility in their definition than the Privacy Rule does. The Common Rule definition says that as long as the identity of the subject is or may readily be ascertained by the investigator or associated with the information, that information is identifiable, so it may be readily ascertained. The Privacy Rule says, listen, if you have one or more of these 18 HIPAA identifiers, and I’ve included them in the attachment, then your dataset is individually identifiable. And so most times, nine times out of 10, we’re going to be relying on the presence of any of the HIPAA identifiers as the finding that the dataset or the information being collected is individually identifiable. Now recall I mentioned that there’s certain exceptions that are outlined in the privacy regulations regarding when authorization is not required. And these are the four; 1) If an investigator for an individual is conducting reviews preparatory to research, a written authorization from the individual is not required. Now what are reviews preparatory to research? They are not pilot studies. They are not research. That’s the important thing. You’re going into medical records or going into files, you are looking at individually identifiable health information but the purpose that you’re doing this is to be able to determine if it’s feasible to conduct a research study, feasible to prepare a protocol where you have sufficient numbers of individuals with whatever it is, the diagnosis that you’re looking at. That’s what you’re looking at when you’re doing a review preparatory to research. You are not allowed to contact the subjects, use this information to contact the subjects. The information cannot leave the VA and there’s certain adaptations that you need to make in order to be able to access this information. One thing that I, myself, honestly am not clear on is for an individual whose conducting reviews preparatory to research, do they have to provide these statements to anybody in particular or is this something that they just need to keep in their files so if they’re ever asked to document that, indeed, they met these criteria. And I know Kim or Karen if either of you want to chime in on that. Kim, any thoughts?

**Kimberly:** The ascertation [phonetic], sorry, the assurance that the actual principle investigator gives to actually do the preparatory to research, the kind of documentation and administrative component of that, we leave to the facilities discretion. But basically, if there’s a written request, it should be given to the data owner. So if there’s something like an MVP database it would go to the actual owners of that database. And if it’s something like [unintelligible 22:59] the facility could decide that they may want their IRB administration or have a document in the research files or they could even have the privacy officer involved in that.

**Soundia:** [unintelligible 23:13] helpful.

**Dr. Karen Jeans:** And hi, this is Karen, I want to just add on that preparatory to research activities is a HIPAA term. It’s not research in terms of human subject protection issue so when you’re hearing about those types of activities it truly is concerning the HIPAA aspect. And something Soundia said is something I really want to emphasize because it is not research and so if you’re trying to do a presentation or a publication resulting from a preparatory activity, then it probably is not preparatory to research. Because it really is only there to basically determine the ability or help define a research question, but it’s not there to do the research itself.

**Soundia:** Excellent. Good point. Thank you Karen. Another situation whereby the regulations allow you to proceed without obtaining written authorization from a subject is if you’re doing research on decedent information. Now unlike preparatory to research, this is research. You’re conducting a research study but you’re only accessing information on individuals who have deceased. So this research would not be subject to the Common Rule because IRB’s oversee research on human subjects, living human subjects. But it would, here in VA, right we have our research committee, so this research activity would fall under the oversight of the research and development committee. So you would still be writing a protocol, submitting this information to someone to review. For research on decedent’s information, you have to certify that the PHI is necessary to conduct the activity. You have to attest that the individuals are, indeed, dead. That you’re not going and looking at individuals who are living as well as those deceased and parsing out those who are deceased and sometimes you still need the total population as your denominator. That’s not what’s going on. You’re only looking at information on individuals who have deceased and you have to attest that the information will only be used on research involving deceased individuals. All right so that’s our second instance where the regulations don’t require an authorization. The third instance is using a limited dataset with a date use agreement. So what is a limited dataset? Well remember when we talked about individually identifiable information, we said that if you are obtaining one or more of the 18 HIPAA identifiers, that dataset is identifiable. Okay? Then if you receive no identifiers it follows that dataset is de-identified. So a limited dataset kind of falls in-between the two but maybe closer to still de-identified because you’re only allowed to include a few select data elements, identifiable data elements, and that is; dates, state, city, and five or nine digit zip codes. So if your dataset is limited to those identifiers, you can have other information, but in terms of identifiers, you can only have those identifiers. And you have a data use agreement and your data use agreement is going to spell out the protections for that data; it’s going to spell out who can receive it and how that information can be used and how that information will be destroyed, all of those things, then HIPAA does not, or the Privacy Rule does not, require a written authorization. And then the final instance whereby, for research purposes we’re talking about, whereby you can proceed without a written authorization is if your IRB or privacy board approves a waiver of HIPAA, okay? And we’re going to talk about that next, well in a few slides.

So how is an authorization documented for VA research? Now if you recall for informed consent I said you don’t have to use the 10-1086 here at the VA. There’s not a required form that you have to use. For HIPAA that’s not the case. Here in VA, you have to use the VA form 10-0493, which is the authorization for use and release of individually identifiable health information for Veterans health administration research, okay? You have to use that for any new studies or any study essentially approved after March 12, 2015. Where is that date from? That is the date when everyone has to become compliant with the revised 1200.05, the one we’re using now. Remember it was published in I think November 2014 and we gave everyone about 90 days and then as of March 12, everyone had to come in compliance with that and one of the requirements was that it mandated the use of this form for all HIPAA authorizations. Okay? The IRB does not approve the authorization. It reviews it to ensure consistency with other study documents but it doesn’t approve it per se. The privacy officer reviews it as well and the privacy officer must sign off on the HIPAA authorization as part of the IRB releasing the package, the approval package. I have a link here for the form. What I haven’t discussed yet, and we’re about to, is whose required to sign the authorization, okay? If a written authorization is required, then the Privacy Rule says that the authorization must be signed and dated by the individual to whom the information or record pertains or their personal representative. Unlike the informed consent form, there’s not a counter signature. The person whose obtaining the authorization does not sign the form, okay? It’s signed by the individual or their personal representative and I want to speak briefly, I’m going to ask Kim again to chime in, because there’s an important distinction between the personal representative, who is the person who is authorized to sign the HIPAA form on behalf of the subject, prospective subject, and the legally authorized representative, which is what you saw in the informed consent requirements. [unintelligible 29:23] the subject or their legally authorized representative could sign the form. Kim, if you could chime in a little bit and explain to us what is, you know, briefly, what is the difference, I know there’s a lot of legalese here, but what is the difference between an LAR and a PR?

**Kimberly:** I guess the easiest way is to explain it, it’s analogous to all thumbs are fingers but not all fingers are thumbs. So basically you have a situation where you have, under HIPAA, you have a personal representative who actually acts as the agent of the individual and they can step into their shoes and generally they secured a power of attorney to actually act as the individual’s agent. Whereas you have a legally authorized representative which doesn’t necessarily, so all personal representatives are legally authorized representatives but not all legally authorized representatives are personal representatives because a spouse can be a legally authorized representative but they may not be the individual’s personal representative. Like they’re not actually, they don’t have a power of attorney over the actual individual. Does that make sense?

**Soundia:** It does. It does. Let me restate what you said. We may have situations where, for the consent purposes, the legally authorized representative may be the personal representative but they may not be. Because if that individual doesn’t have a designated personal representative the next person on the list could be their spouse, their children, so on and so forth. Whereas for HIPAA, the only person, other than the subject, who can sign that form is the personal representative. Did I get that right?

**Kimberly:** Exactly.

**Soundia:** Thank you. So now I have a question for you. How often, then, do we see cases, in VA research whereby, you know, unknowingly, a legally authorized representative who has not been designated, right, a PR, they don’t have power of attorney. The subject does not have a personal representative, they’re incapacitated, they have diminished capacity and so on and so forth and so their legally authorized representative signs the consent form and then proceeds to sign the HIPAA form. How often does that happen? And what can be done in instances like that? How do we either mitigate that situation? How do we prevent it from happening?

**Kimberly:** That’s kind of, I think, a sticky wicket in the sense that when you have someone who is actually, if they’re of diminished capacity, it depends on the level of incapacitation. If they’ve been fully incapacitated by an actual clinician then the only one who should be able to sign is the personal representative. Because the power of attorney doesn’t actually, from lack of a better phrase, kick in, necessarily, until the actual individual has been deemed incapacitated. Depending on the power of attorney designation, there’s several different types that you can actually have, so it’s something, I’m hoping, I don’t know any statistics on it but I’m hoping it’s something that happens infrequently and that if there’s any question about it that the actual study staff actually contact the privacy officer at the facility to get further clarification.

**Soundia:** Sounds good. Thank you. All right. So now we’re going to move on to the main act. And we’re going to start with the HIPAA waivers because we just spoke about HIPAA authorization. So we talked about the four instances, I believe there were four, when you did not need, when the regulations allow you to not obtain the written authorization. And one of those was when the IRB, or the privacy board, approves a waiver or alteration, or alterations of HIPAA. If the IRB or privacy board approves a waiver of HIPAA, then you would not need to obtain the written authorization from the individual. And there’s certain key criteria that have to be met in order for the IRB, or privacy board, to approve that waiver. They’re all listed here on these two slides, 14 and 15, or you may have 13 and 14 because I added that lovely chart diagram. But in any case, all the requirements for approving a waiver are listed here. I’m not going to spend time going through all of them. I’m really going to just stick to some of the key ones that end up really driving the decision of whether the IRB or privacy board can approve the waiver. And that is, let’s start with 3a); In order to approve a waiver of HIPAA, or an alteration, the IRB, or privacy board, has to document that the use or disclosure of the requested information involves no more than minimal risk to the privacy of individuals based on at least the presence of the following elements. And then it goes on to describe elements that all really have to do with making sure that there are adequate protections in place to ensure the privacy of the individual’s data. That there are plans in place for adequate destruction of the data and that any disclosures of the data are in line with what’s permitted in the Privacy Rule. So it’s important, therefore, that the plan that’s submitted with the HIPAA waiver and any references of the protocol that describe how the data is protected, the IRB needs to be able to determine from that information submitted and come up with a determination that there’s no more than minimal risk to the privacy of individuals. The other criteria that tends to really drive the decision of whether the IRB or privacy board can approve a waiver is the second one, b) that I’ve highlighted, where it says the research cannot practicably be conducted without the waiver. Now we’re going to see this word practicably come up often in waivers and, unfortunately, there’s no regulatory definition for what practicably means. I think, honestly, it would make all our life a lot easier if there was, but there isn’t. And so really it’s up to the interpretation of the IRB based on the information they’ve received from the study team. Now one thing, though, that there is general consensus in the regulating community, is that practicably is not synonymous with inconvenient. You can’t just say just because something’s inconvenient, therefore, it’s impracticable. So there’s general consensus about that. But in terms of what factors go into the IRB decision when determining if something is practicable or not, that’s what’s going to really drive the decision of granting this waiver and a number of other waivers. And one thing to really stress is that the criteria is that the research could not practicably be conducted without the waiver. This is key because sometimes, and even I myself sometimes, get tripped up and really start only focusing on consent, is it possible, is it practicable to get the consent or not? But it’s larger than that. It’s if we did not give you this waiver, could you really conduct this research study? Is there any other way this research study could be done if we didn’t give you the waiver? So just some things to think about. In terms of the form itself, the IRB chair, or a designated member of the IRB, has to sign off on the form. And then here at the VA central IRB, and I’m sure in other local facilities, our privacy officer, either Kim or Stephanie, they will not issue their final certification for approval of the study until they see the approval document from the IRB approving the study, as well as the signed HIPAA waiver and any other forms that require signature if a waiver was granted.

I’ve included here a link to the VA Central IRB form 103 which is an example of a waiver and/alteration of HIPAA form. I’m not going to go into it because I don’t want to spend time. It’s just an example. I’m not saying it’s the best form but it’s a form that we use often and we’ve been using it for a year and to the extent that, you know, from this lecture you decide to maybe revise some of your forms, you want to look at an example, you know, there’s the link for the form. And I included it in my email that I sent out to folks with all the attachments. I don’t think it was included in the documents I sent Heidi but it’s on the VA Central IRB webpage. So it’s publically available, you can find it.

Some additional forms that are optional here at the VA. There is another form, a VA form 10-0521 which is also a waiver of HIPAA authorization request. So this is another example you can use if you’re looking to compare your current form to other forms. There’s no mandate to use this form but it’s available for your use. And then finally, the VA form 10-10116 which is a revocation of authorization form, is also a form that’s available for your use. I’ve included all that there for you all.

All right let’s switch gears now and go back to the Common Rule and talk about waivers that are allowed under the Common Rule. If you recall, one of the things I mentioned at the beginning was informed consent must be prospectively sought from a human subject before engaging them in research, unless the IRB approves a waiver, okay? And there are two criteria under which the IRB can approve either a waiver or alterations of informed consent. The first one is if the research or demonstration project is conducted by or subject to the approval of a state or local government, and the study is designed to evaluate, assess public benefit of service programs, anything to do with that, procedures for obtaining the benefits, possible changes, alternatives to the programs or procedures, changes in the methods or levels of payment, things to do with evaluating and assessing for public benefit of service program, and the research could not practicably be carried out without the waiver alteration. Again, here’s our lovely word practicably.

So in order to use this, in order to waive consent, and what waive consent means is you will not provide the subject, prospective subjects, with any information to make an informed decision about whether he or she wants to participate in the research. So in order to not have to do that you have to meet either this criteria where it’s a public benefit program, research on a public benefit program, or there’s an alternative option and that is research that is minimal risk. The second scenario under which an IRB can approve a waiver or alteration of informed consent is for minimal risk research that meets these criteria listed here. Well 1) It’s been deemed a minimal risk study, 2) the research or alteration will not adversely affect the rights and welfare of the subjects, 3) the research cannot practicably be carried out without the waiver or alteration, and then 4) when appropriate subjects will be provided with additional pertinent information after they participate. So these are the two scenarios. Only two scenarios in the Common Rule under which the IRB can approve a complete waiver of informed consent and/or alteration of informed consent. Alteration essentially means that maybe they say that certain of those two part elements that we talked about do not need to be provided to the subject or included in the informed consent process.

What does the revised Common Rule say? Because come January 21, 2019, if we approve a waiver, we’re going to have to make sure it meets the criteria in the revised Common Rule. So the two scenarios are similar; we have research on public benefit and service programs for the most part that remains unchanged. There’s a caveat which I’m going to talk about in a second dealing with waivers and alterations in general. But the requirements for research on public benefit and service programs, the specific requirements you have to meet, for the most part, are the same. For our minimal risk research, remember if your research is minimal risk, the IRB can approve a waiver or alteration if it meets the same four criteria that we had before. Those remain unchanged. But now there’s an additional criteria and they slipped it into number three. But I’ve highlighted it in red and essentially it’s if the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format. So if your research now, in order to qualify for a waiver or alteration of informed consent under the minimal risk criteria, the IRB has to factor in one additional item, or aspect. And that is if you’re using identifiable biospecimens or identifiable data, they have to basically state and document that the research has to be conducted using identifiable data. The research could not be carried out if it did not have access to, identifiable information. So this is something as you guys start thinking about what you may have to change in the future to be ready for January 21st, your HIPAA waiver forms, your waiver of informed consent form, I’m sorry, would be one of the items that you would want to revise to make sure that you include this additional criteria.

What else might you need to revise? Well it’s this thing I mentioned, there’s a caveat for waivers now. Broadly speaking, the new revised Common Rule introduces a concept called broad consent. And I’m not going to talk about that, Kristina has a wonderful lecture planned tomorrow which she’s going to go into informed consent and broad consent. But there’s this new option for subjects to provide informed consent and that’s under broad consent. And it’s specific to the storage, maintenance, and secondary use of identifiable data or specimens. In cases where a broad consent procedure is used, the IRB is not allowed to waive or alter any of the elements required for broad consent. And again, Kristina is going to be going over this in terms of what elements are required for broad consent. But the IRB is not allowed to waive, alter any of those elements. If a subject was approached and asked to give broad consent for the storage, maintenance, or secondary use of their identifiable information or specimens and the subject says no thanks, I am not interested, the IRB cannot subsequently waive their consent. They cannot subsequently say you can go ahead and use their specimens or their data for research because the subject was asked and they said no. So those are some of the caveats under the revised Common Rule when it comes to waivers. However with the exception of broad consent, for the most part, the IRB can approve a complete waiver of informed consent if the required criteria has been met.

There is a caveat for alteration of consent. And that is that the IRB, under the revised Common Rule, the IRB is not allowed to approve a consent procedure that admits or alters any of the general requirements of informed consent found in 38 CFR 16.116 (a). What are those general requirements? The general requirements are really what drives the consent process, okay? And if you look at this list a lot of these elements should sound very familiar because this is what I showcased when we looked at the concepts of respect for persons in the Belmont report. That the information is provided to subjects under situations where the subject has a sufficient opportunity to decide whether they want to participate that minimizes coersion, undue influence, does not include any exculpatory language through which the subject is made to appear to waive any of their rights or release the investigator from liability from negligence. Information has to be provided to subjects in a language that they can understand and sufficient information has to be provided to allow them to make an informed decision. So in instances effective January 21st where the IRB approves an alteration of informed consent that says you can remove this element, you don’t have to include this element as part of the informed consent process, they are not allowed to alter any of these requirements related to the informed consent process, okay? The other thing that they’re not allowed to alter or remove is a short summary of key information related to participation in the study that is now required to be provided upfront as part of the consent process. This is a requirement that’s going to be, you’ll be seeing this in the revised Common Rule and, again, Kristina will go over this tomorrow at length. But these are the things that under the revised Common Rule, the IRB is not allowed to alter.

Now this one is a little interesting because the revised Common Rule allows for the IRB to approve the use of the subjects information as well as access to their biospecimens or their private information for screening and recruiting activities, right, for eligibility determinations essentially, without obtaining the subjects informed consent prospectively, provided that certain criteria are met. One being the investigator obtains the information through oral or written communication with the prospective subject. So they’re obtaining that information directly from the subject, or the investigator obtained the identifiable information or identified biospecimen, by accessing records or stored specimens. They’re not going in obtaining them de novo or prospectively. These activities, right, recruiting and screening activities, using information to be able to determine eligibility, this right now, we do these activities all under a waiver of informed consent. Again remember, anytime you want to access subject’s information without their informed consent you need a waiver or it has to be excepted. And so right now we do this under a waiver of informed consent. So what we’re being told now is that with the revised Common Rule you won’t need a waiver for screening and recruiting activities. This doesn’t mean you won’t need a waiver for other activities, but not for screening and recruiting activities if they meet this requirement, these requirements. What’s interesting is, remember, full disclosure Common Rule and Privacy Rule. So we would still need a waiver for HIPAA, unless HIPAA changes it’s regulations. So while the IRB can now approve the use of screening and recruiting without informed consent they won’t need a waiver under the revised Common Rule, you will still need a HIPAA waiver to conduct those recruitment activities. Just something to remember, always you have two hats that we’re wearing here.

So for FDA regulated research, if you recall, I said there were very few exceptions to informed consent requirements for FDA regulated research. There are four in particular and three of those four all deal with emergency situations. Emergency use of a test article, emergency research, and the use of an investigational in vitro diagnostic device to identify chemical, biological, or radiological, or nuclear agents in emergency situations. For these situations, and there are certain requirements that have to be met, it’s not just a blanket, you know, but the FDA allows for these activities to proceed without obtaining the prospective informed consent from the subject provided certain requirements are met. The fourth option, bullet number two, is 10 USC 1107(f) grants the President unique authority to waive consent for the administration of an investigational new drug. So as a member of the armed forces during a particular military operation, if the President determines that obtaining consent is not in the interest of national security. So right now these are the only four instances in which, for FDA regulated research, you can proceed without obtaining the prior informed consent of subjects. If you notice, we’re not seeing some of the language that we’ve seen in the Common Rule but, luckily, that is about to change or is in the process of changing. Let’s use that terminology.

So if you remember, for informed consent, to waive informed consent under the Common Rule you had two options. One was the research on public benefit. The other option was minimal risk research that met certain criteria. And so effective July 2017, the FDA published a guidance document that says that basically for minimal risk research we immediately, effective immediately, we will allow IRBs, or we will not object to IRBs that waive informed consent for minimal risk research provided these criteria are met for FDA regulated research. Similarly, we will not object and we will exercise enforcement discretion for any sponsors that submit studies, results of studies to us, for minimal risk research where these criteria have been met. And so this is FDA starting to realign some of their regulations, particularly this one, with the Common Rule regulations for waiving informed consent for minimal risk research. And this all came about because of 21st Century Cures back in December 2016. There were some amendments to the Food and Drug Cosmetic Act, there were multiple, but one of the amendments revised the language that finally allowed FDA to seek authority to permit the exception of informed consent for this new category. Remember prior to this, they only had the ability to except informed consent in those four cases that we talked about, the presidential waiver and the three emergency uses. But with the amendment, so the Food, Drug, and Cosmetic Act, they now have the ability to waive consent for minimal risk research that meets these criteria. Now the FDA has not yet revised the actual regulations. That’s something they are in the process of working on. But they have said that until then, the guidance document will provide evidence to support the fact that they will, effective immediately essentially, you can proceed with using the minimal risk waiver for FDA regulated research.

The second instance I found related to our research that would be interesting, where FDA again said that we will exercise enforcement discretion for informed consent, is in dealing with left over human specimens. I think it was in 2006 FDA published a guidance document that says that in instances when left over human specimens are used for research that is exempt from the investigational device exemptions and those specimens are not individually identifiable, we will not object to sponsors using that information without the informed consent of the individual. Now for us under the Common Rule regulation, we’re probably thinking that if the information is not identifiable, if it’s existing, it probably wouldn’t fall under our definition of human subjects research. FDA has a different definition of human subjects research and that’s why they had to, in order to allow sponsors to use this without, use these left over specimens, not individually identifiable specimens but essentially allowing them to use specimens for this research, they had to create this document saying that they would exercise enforcement discretion. Because the FDA definition of a human participant states that a human participant is one who participates in an investigation either as an individual or whom or on whose specimens an investigational device is used or as a control. And so because of this, sponsors who wanted to use the specimens to be able to test various devices and such, had a hard time being able to use it because they would have to obtain the prospective consent from subjects. And so now, with this guidance document, this is not new, this was published in 2006, but I included it so we could be complete in terms of how FDA approaches informed consent for research purposes here.

All right waiver of documentation of consent. There are two instances under which an IRB can waive documentation of consent. Before I get into them, I want to talk about what waiving documentation of consent means. Oftentimes people refer to this as verbal consent. Let me be clear, waiving documentation of consent does not mean you are not obtaining the consent of the individual. You are still going to be providing them with the information they need to make an informed decision regarding whether they wish to participate in the research study or not. The only thing you’re waiving is the documentation component. The IRB, under certain scenarios, can waive the requirement that the investigator obtains the signed informed consent form for some of the subjects. If it finds either that 1) the only record linking the subject and the research would be the informed consent form and the principle risk would be potential harm resulting from such a breach, or that the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. The first one is interesting because, and I’m going to ask Karen maybe if she has any ideas or thoughts, some examples she can give people of when we typically would see that being used, whereby the only record linking the subject from the research is the consent form and the principle risk is potential harm resulting from a breach of confidentiality.

**Dr. Karen Jeans:** Okay. [unintelligible 56:16]. Yeah because we so commonly use the second one and [unintelligible 56:24].

**Dr. Patrice Longenecker:** Hopefully you can hear me. I’ll come close to the computer. So an example of one you may want to waive documentation of consent using the first criteria. For instance, if you have a study that’s going to interview sex workers or interview individuals who may be doing illegal activities. So having just that signed documentation of their involvement or their consent in the study, puts them at legal risk. So you still get their consent. You still give them all the information they need to consent to the study you just don’t document that consent with a signature.

**Soundia:** Thank you, Patrice, great example. And then the second one, like Karen said, the one we typically use more in the research we conduct here at the VA is where the research presents minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. And this one would be typically things like focus groups and surveys, interviews, things whereby the mere participation of the subject normally indicates their willingness to participate. Anybody else think of any other examples per se?

**Dr. Karen Jeans:** I think what Petrice brought up was a really good example because it really shows the difference between, this first one does not have the qualifier of minimal risk, and the second one does. So that’s a key issue to remember in these two. [unintelligible 57:43].

**Dr. Patrice Longenecker:** Especially when you think about our Veterans who may be involved in some illegal activities or questionable activities and you still want to include them in your research. Having that document often times scares our subjects because they think, well the government knows I’m in this study and now the government knows I’m doing something that I may not, or should not, be doing. So this is just an additional way to protect our subjects because you don’t have that link.

**Soundia**: Perfect. Thank you. What does the revised Common Rule require when it comes to waiver of documentation of consent? Instead of two options, there are now three. The first two options are similar to the ones we just spoke about, nothing’s changed there so that is good. There’s now though a third option for waiving documentation of informed consent and that is if the subjects, or their legally authorized representatives, are members of a distinct cultural group or community in which signing forms is not the norm, the research presents no more than minimal risk of harm to subjects, and there is an appropriate alternative mechanism for documenting that informed consent was obtained. So this is going to be a new option available as of January 21st for waiving documentation of consent. I think for this one we might have to wait to see some guidance from OHRP on what would constitute, you know, these alternative mechanisms that they would deem, you know, appropriate to be able to constitute the public for documentation of informed consent.

**Dr. Petrice Longenecker:** Usually international research.

**Soundia:** International research Petrice says would sometimes qualify for this, so this is good. What do the FDA regulations say with respect to waiving documentation of consent? There are two scenarios under FDA regulated research for waiving documentation of informed consent. I’ll talk about the second one first and that’s where, the IRB finds that the requirements for an exception of informed consent for emergency research are met. In that instance you would not need documentation of consent. They’ve already excepted informed consent. Again there are requirements that have to be met, it’s not blanket, but that’s one instance. And the second one is, or the first one on this page is, that the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. Similar to what we saw for the Common Rule.

Now I promised you guys I would touch on this so I circled back to it. For VA research, if you remember I said that VA approved research requires, unless the IRB waives documentation of consent, it requires a signature from both the individual, the subject, or the subjects legally authorized representative, as well as the individual obtaining consent unless the IRB specifically waives that signature of the individual obtaining consent. That’s the only thing the IRB can waive. They can’t waive the person’s, the subject’s, signed consent unless they’ve totally just waived documentation of consent. Now this is only allowable in cases, instances, where there is no physical contact with the subject, okay? That’s the only time the IRB could waive this. This would be found in the IRB documentation that they’ve made this waiver and then one could proceed. If we’re thinking about any specific examples about how this might be used, I think one that we’ve used before is in instances where maybe the study team is in contact with the subject over the phone or they’ve consented the subject over the phone, they have not seen, they’re not in physical contact with the subject. The subject signs the consent form, agrees to participate in the research but they won’t be coming in until the later date. And so this might be an example of how waiving the signature of the individual obtaining consent could be used rather than having the consent form returned and then somebody has to sign the form, the dates are different. It can kind of create a lot of compliance confusion. This is an example that might be used for justifying waiving the signature of the individual obtaining consent.

I’ve included the VA Central IRB form 112b which is an example of a waiver of documentation of informed consent form. It was included again in the email that I sent out. It’s a publicly available form that’s on the VA Central IRB website so you can go to it if you’re looking at just comparing your current form to what another IRB uses.

All right. So I call this my cheat sheet. Now this cheat sheet is not about what are the requirements for approving a waiver. That actually includes the specific requirements from, the regulatory text and that was included in the handout. This is more a way of framing when is it most appropriate to request to do what. Because I think there’s a lot of confusion out there in terms of when is it appropriate to request a waiver of informed consent or alteration of informed consent versus a waiver of documentation of consent. So brief, in brief, a waiver of informed consent would be requested most appropriately when you are not able to obtain the informed consent from the subject for all or a portion of the research study or when you need to omit elements required for informed consent. So with this, you do not plan on providing the subject with information for them to make an informed decision regarding whether they want to participate in the study or not, okay? We’re going to be looking at various aspects of the study. We’re going to see if it’s appropriate or not. One of the instances where it’s probably appropriate to request a waiver or alteration of informed consent is if you want to conduct recruitment and screening activities, go into records, and you want to do that without the subjects prospective permission. Waiver of documentation of consent. That‘s the proper terminology. Many of you refer to it as verbal consent. Just want to make sure though that people understand that with waiver of documentation of consent, you’re still obtaining the subject’s consent in the sense that you’re still conducting the informed consent process. You are providing the subject with sufficient information to make an informed decision about whether they want to participate in the study or not. The only thing you’re not doing, the IRB will either approve, or they won’t approve, but we’re hoping they will approve, your request where you don’t have to obtain the subjects signature on the form. And then lastly, remember, full disclosure, waiver or alteration of HIPAAs are needed in instances when you’re not able to obtain a signed authorization form for the subject or you want to omit certain elements of what’s required for a valid authorization. Again for all of these three, requirements have to be met. So it’s not automatic but these are the types of situations that you would want to request each of the specific waivers.

So now we’re going on to our case studies. We have some people excited to hear about that. All right. We’ve got three case studies, like I said, but each case study has multiple questions. I’m going to say in advance, these case studies some of them are straight forward, many of them are not and that’s because that’s really the way, the nature of waivers. Sometimes it’s not straightforward. Oftentimes the IRB is trying to steal information from the protocol from the request. They have to go back and forth with the investigator to make sure they have enough information to justify approving the waiver request. So case study number one. An investigator at the Old Glory VA is conducting a minimal risk study investigating whether use of a smartphone can improve delivery of physical therapy in Veterans with prosthetic devices that are already scheduled to begin physical therapy. Veteran medical records will be accessed to identify eligible subjects. 150 Veterans will be enrolled into a group using a smart phone app in addition to their regularly scheduled therapy. The study team plans on conducting face-to-face interviews with both participants and providers in the smart phone app group at the end of the study about their experience with the device. Medical records from 500 Veterans that are located around the country who are also undergoing physical therapy with prosthetic devices will be accessed to serve as controls. There’s no interaction or intervention for research purposes that will occur with the Veterans enrolled in the control group. So with those 500 Veterans there will be no interaction or intervention, and no data will leave the VA. Our question is in order to identify eligible Veteran subjects for the study, the study team will need to obtain: A) a waiver of informed consent for recruitment purposes, B) a waiver of HIPAA for recruitment purposes, C) both a waiver of informed consent and HIPAA for recruitment purposes or, D) neither.

**Heidi:** And responses are coming in a little bit slowly. We’ll give you all just a few moments to read through this, make your decision. Remember this is anonymous. We don’t know who is answering what so feel free to send in what you feel is the correct answer here. We’ll go through what everyone sent in in just a moment here. And please just click on the radio button next to what you think your response is on the poll. You don’t need to send it in through the questions pane. We’ll count them if you click on those radio buttons on your screen next to your selected answer. And it looks like we have slowed down here so I’m going to close this poll out and what we’re seeing is 8% of the audience saying a waiver of informed consent for research purposes, 16% of the audience say a waiver of HIPAA for recruitment purposes, 61% of the audience saying a waiver of informed consent and HIPAA for recruitment purposes, and 15% of the audience saying neither. Thank you everyone.

**Soundia:** Excellent. Thank you Heidi. And the correct answer is C. A waiver of informed consent and HIPAA for recruitment purposes. Remember now, we’re a covered entity, we always need to consider both HIPAA and informed consent when we’re involving human subjects in a research study. And in this case they wanted to be able to go into the medical record and identify eligible Veteran subjects for the study. They were doing this prior to contacting them for the study. They were doing this to be able to see who do we need to contact. When you’re going to be accessing subject information without their consent you need a waiver of informed consent and a waiver for HIPAA, okay? I hope that makes sense.

Our second poll. The study team has requested a waiver of consent and HIPAA for the interviews with providers at the end of the study. The providers will be asked to give their opinions about their experience with the app, the smart phone app. Providers will not be asked about individual patients. Should the IRB approve the waiver requests? They’ve been asked for both a request for a waiver for HIPAA and consent.

**Heidi:** And responses are coming in here. We’ll give everyone a few moments to respond before we close the poll out. And it looks like we’ve slowed down here so I’m going to close this out and what we’re seeing is 52% of the audience saying yes, 41% of the audience saying no, and 6% saying they’re not sure. Thank you everyone.

**Soundia:** And thank you. And this is great. And this is what we love to see. We agreed with the 41% of you that said no. They should not approve the waiver request. And this was a complicated one so we’re going to go into why. Why we feel the answer is no. So the question was should the IRB approve the request to waive both consent and HIPAA for interviews with the providers. Let’s tackle the provider interviews first for consent. Remember there are two options for waiving consent; either for research conducted on public benefits, which this is not the case here, or minimal risk studies, okay? So I would argue this falls into the minimal risk studies and, therefore, then should the IRB waive consent for this minimal risk study or activity? Does it meet the criteria? The first criteria is, the research involves no more than minimal risk, we agree. The second one is the waiver alteration will not adversely affect the rights and welfare of the subject. Seems not. Third one, and this is where we’re going to keep coming back to, the research could not practicably be carried out without the waiver or alteration. If the study team was not granted the ability to not get the informed consent from this population, it cannot conduct the study. And in this case, they’re interviewing the providers face to face at the end of the study. There’s nothing that prevents them from being able to explain to the providers what they’re doing and why. And so a waiver of consent would not be appropriate because it is not impracticable to conduct the study without the waiver. It’s very easy to be able to get the consent in this case. HIPAA, what about HIPAA? In this case we were told that the providers will be asked to give their opinions and experience with the app. The providers will not be asked about individual patients. And if you remember, when we talked earlier on in the training about an hour ago, we asked Kim, when we were talking about individually identifiable health information, HIPAA does not apply to providers when one is not obtaining any health information from it. And so in this example, we’re not obtaining any health information from them. So that’s why the answer is no. It doesn’t meet the requirements for a waiver of consent in our opinion and HIPAA is not applicable. So we’re starting to get into some of the, you know, the nuances and the gray areas early on these polls.

Poll three. The study team has requested a waiver of informed consent and HIPAA to access data from the medical records for the individuals in the control group. Remember there were 500 individuals located all across the U.S. No intervention or interaction was going to be done with them. The only thing the study team needs to do is access their medical records so they can use them as controls. The study team has requested the waiver of informed consent and HIPAA to access the data. Should the IRB approve their request?

**Heidi:** And the options here are A) yes, B) no, C) I’m not sure. We’ll give everyone a few moments to respond and we’ll go through the results. And it looks like we’ve slowed down here so I’m going to close the poll. And what we’re seeing is 83% of the audience saying yes, 13% of the audience saying no, and 4% saying they’re not sure. Thank you everyone.

**Soundia:** Excellent. Thank you and we agreed with the 83% who said yes. That we feel that the IRB should grant both the waiver of consent and the waiver of HIPAA. Again this study, in terms of waiver of informed consent requirements, this would fall under the minimal risk study, not the public benefit. And in terms of whether the research could not be practically carried out without the waiver. We would contend that it probably could not be carried out practicably speaking without the waiver because individuals are all over the country. There’s no interaction or intervention with these individuals, these 500 Veterans. We may not even have the most up-to-date contact information for these Veterans so it really may not be practical to conduct the activity without the waiver. In terms of HIPAA, same thing the practicability issue. We’d have to contact individuals throughout the country in order to be able to access their medical records for this minimal risk study and so we’d probably meet the requirements for a waiver of HIPAA as well.

All right. Case study number two. An investigator at the Red, White, and Blue VA plans to administer a survey in a minimal risk study to 2000 Veterans with major limb amputation to assess patterns of prosthesis use, function, and satisfaction with the care they received at the VA. The study team has requested waivers of consent and HIPAA for recruitment purposes to access the Veteran’s medical records to determine eligibility. Study packets, including the survey and a pre-paid stamped envelope for returning completed surveys, will be mailed, excuse me, to eligible participants. The study team will call Veterans to make sure they received the packet and ask them if they have any questions about the study, including whether they would like to complete the survey over the phone. The study team has requested a waiver of consent for administration of the survey. Should the IRB approve their request?

**Heidi:** And the responses here are A) yes, B) no, or C) no, but the study may be eligible for a waiver of documentation of consent. And again we’ll give everyone a few moments to respond before we close the poll out and go through the results. And it looks like we’re slowing down here so I’m going to close this out. And what we’re seeing is 22% of the audience saying yes, 16% of the audience saying no, and 62% of the audience saying no but the study may be eligible for a waiver of documentation. Thank you everyone.

**Soundia:** Excellent. Thank you. And we agree with the 62% who said no. The IRB should not approve the waiver of consent for administration of the survey but the study may be eligible for waiver of documentation of consent. Let me just clarify, again, that when you’re requesting a waiver of consent what you’re saying is I’m not going to provide the subject with any information about the study so that they can make an informed decision, okay? In order to approve a waiver, two options, research on public benefits or minimal risk research. This would fall into the minimal risk category. We were told that the issue of impractibility though comes into play again. Could the research be conducted without the waiver? Is it impractical to conduct the research without the waiver? They are going to be mailing the subjects letters, well surveys, the subjects are asked to return those completed surveys. There’s no reason why in that mailing one could not include an informed consent form or an information sheet that includes information on why we’re conducting this study, how the information will be used, whether you’ll receive any payment for participation or not. There’s no reason why you could not include that to be able to conduct the consent process. Why we feel the study may be eligible for a waiver of documentation of consent is if you don’t want to get the signature back, you don’t want to have them sign the consent form, there are two options for waiving documentation of consent. One, the only record linking the subject and the research would be consent document and the principle risk would be potential harm resulting from breach of confidentiality, doesn’t apply here because of the survey as another document. Secondly, the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. Normally completing a survey is something that would not require consent outside of the research context. You agreed to complete it, you complete it, you’re done.

Question number two. What about HIPAA? We’re a covered entity, we’ve always got to think about both things. Should the study team include a HIPAA authorization form in the mail, or request a waiver of HIPAA for the administration of the surveys?

**Heidi:** And the options here are; A) include a HIPAA form and hope that it is returned, B) request a waiver of HIPAA, or this one is tricky, C) I’m not sure. We’ll give everyone a few moments to respond before we close the poll out and go through the results. It looks like we’re slowing down here so I’m going to close this out and what we’re seeing is 15% of the audience saying include a HIPAA form and hope it is returned, 65% of the audience saying request a waiver of HIPAA, and 20% saying this one is tricky, I’m not sure. Thank you everyone.

**Soundia:** Thank you.

**Dr. Karen Jeans:** So this is Karen. I came up with this one so blame me for this one. And so this one, this one is indeed tricky. I put this in here because one of the things that Soundia talked about earlier was a waiver of informed consent and we have a waiver of informed consent and we have a waiver of documentation of consent, and when we’re talking about a waiver of informed consent or a waiver or alteration, signature and date is not part of it. That’s just not. If you’re going to do that, then you do a waiver of documentation of informed consent. HIPAA is not the Common Rule. And so under HIPAA, you have, in terms of a valid authorization, there are six core elements and three statements that are required for a disclosure of PHI. And so this question and Kim does not know that I am going to ask her this question because this is why, again, we value our relationships so much with privacy. The question that I will have and I would like Kim to comment on, is that in terms of VHA and privacy, is it acceptable to request an alteration of HIPAA authorization since signature and date is one of the core elements of a valid HIPAA authorization and that was not one of the options that I’ve got on this list.

**Kimberly:** The simple answer to that is no. Because what happens is on the authorization, the 10-0493, those authorization requirements actually mirror the elements that we have as requirements in 1605.01 and one of those requirements is signature. So it’s inappropriate to try to do an alteration to remove that signature. So in lieu of that, the alterations for lack of better term, would be to secure an actual waiver of authorization completely so there would be no 10-0493 form involved.

**Dr. Karen Jeans:** Thank you. That is a burning question which we have and we wanted everyone to hear from privacy because, privacy does not, you know, this is again the link between ORD and privacy so Kim thank you very much for that.

**Soundia:**  And it would really be the IRB who in determining whether it’s impracticable to conduct this study without the waiver would make the call and one of the factors they may take into consideration is what happens, and it’s bound to happen, that you get a completed survey returned and you don’t get the HIPAA authorization form returned. Now all of a sudden because you required a signed authorization, you can’t use that data and so it very well maybe that in this case would say you still have to do consent. We’re going to waive documentation of consent because it’s impracticable and that maybe, oh no sorry, impracticable wasn’t an option, isn’t a requirement for documentation, that’s consent. But that for HIPAA this might be a scenario where it is impracticable because it would cause too much confusion and you would end up with too many data points that you can’t use because you did not get the signed authorization returned.

**Dr. Karen Jeans:** And one of the reasons I also made this a case is a lot of times, you know, we’re talking about VA requirements here and a lot of times many of us have dual appointments, you know we’re dual appointees. We are university or other employees of other institutions that are also part of covered entities, or hybrids. And you’ll hear them say well we’re going to weigh the signature as one of the core elements. That’s them. That’s not VA. So just because you hear someone else doing it, doesn’t mean that VA can do it. So that’s another reason we wanted to present this case today. Thank you.

**Soundia:** All right. Our last case study, is two-fold. This is a bit of a long one but let’s get started. Case study three. A VA Investigator is collaborating with DoD on a nationwide study of Veterans returning from war in the past three years that have been seen in PTSD clinics about how their experience in the war has affected their ability to reintegrate into civilian life. Both VA and DoD will identify eligible participants using their personnel and medical record databases. Study packets containing a survey, an information sheet/consent form, and pre-paid return envelopes will be mailed to 5,000 veterans with the goal of receiving 2,500 completed surveys. No intervention or interaction with these participants for research purposes will occur. The 40-item survey includes six to eight questions about military sexual trauma, combat exposure, and illicit drug use. Information will be obtained from participants’ medical records and the survey will ask Veterans to check a box indicating their desire to be contacted to participate in an interview with the study team. A subset of Veterans, about 200, who return the survey will be contacted by phone for an interview. I know this was a long one. Is the administration of the survey eligible for a waiver of documentation of consent? A survey that’s going to be sent in the mail packet.

**Heidi:** And responses are coming in. We’ll give everyone a few moments to respond before we close the poll out and go through the results. Okay it’s look like we’ve slowed down here so I’m going to close this out and what we’re seeing is 42% of the audience saying yes, 30% saying no, and 28% saying more information is needed.

**Soundia:** Excellent. Thank you Heidi. The correct answer is C, more information is needed. And why is that? We’re looking at waiver of documentation of consent. Two options exist for waiving documentation with consent. One either the only record linking the subject with the research is the consent form. That’s not the case here. There’s a survey. Second option, minimal risk research. In order to approve a waiver of documentation of consent, the research presents no more than minimal risk to the subjects. We don’t know in this case if the study is minimal risk. Just because it’s a survey does not mean it’s a minimal risk activity. We’re told that there’s some questionable questions in there. Just because they’re questions about military sexual trauma, combat exposure, illicit drug use, that does not mean that it’s greater than minimal risk either, right? We don’t know. So we need more information.

Second question. The study team has requested that the IRB approve verbal consent, we’re going to use the terminology that people use, from the Veterans that they interview by phone. Should the IRB approve this request? Essentially should the IRB approve a waiver of documentation of consent for the Veterans that they interview by phone?

**Heidi:** And the poll is open. We’ll give everyone a few moments to respond before we close the poll out. And it looks like we’ve slowed down here so I’m going to close it. And what we’re seeing is 57% of the audience saying yes, 12% saying no, and 32% saying more information is needed. Thank you everyone.

**Soundia:** Thank you. And we’re going to agree with those who said C, more information is needed. Again, interviews. We don’t know if the concept of the interviews is going to be a minimal risk activity given the nature of the questions that may be asked. We weren’t told that this was a minimal risk study, remember that. And so without that information, the IRB cannot approve the waiver of consent, see even I have to look at my cheat sheet, without the information, okay? The research is not designed to study public benefit. See I’m getting all confused, geez. Verbal consent is waiver of documentation of consent. The two criteria are minimal risk research, which we don’t know, and that the only record linking the subject and the research is the consent document, okay? See that’s why we should go with written documentation of consent and not use terms like verbal consent. They end up even confusing me.

All right. This is the last part of our case study. Now the study team realizes that this study could provide a wealth of information to the VA on the needs of Veterans returning from war and revises the study to open it up to all Veterans returning from war in the past three years and makes it a minimal risk study, both the surveys and any interviews, so all aspects of the study are now minimal risk. The protocol is revised to include the mailing of annual surveys to these Veterans for the foreseeable future as well as a request to store the data in a repository for future use. The study team requests a waiver of documentation of consent for administration of the annual surveys and for storage of the data for future use. Our question is and this is the last question, should the IRB approve a waiver of documentation of informed consent for the annual surveys and for the future use of the research data?

**Heidi:** And the poll is open. We’ll give everyone a few moments to respond before we close the poll out and go through the results. And it looks like we’re slowing down here so I’m going to close this poll. And what we’re seeing is 27% of the audience saying yes, 38% of the audience saying no, and 35% of the audience is not sure. Thank you everyone.

**Soundia:** Good. Good. We’re going to end this training out with saying, hmmm. And that’s because this is really the realm that we work within. It is so not black and white. Oftentimes we’re trying to really dig in, figure out the details, we’re scratching at our heads, we’re asking for more information in order to make sure that the appropriate authority exists for some of the requests that we receive. So why did we end up with hmmm, C, in this case. For waiving documentation of consent, there are two options, two scenarios; 1) that the only record linking the research and the subject is the consent form. That’s not the case here so that doesn’t qualify, or 2) that it’s minimal risk research that involves procedures, no procedures for which written consent is normally required outside the research context. We know that this is a minimal risk study so we think we’re good. Where we pause is whether the storage of these surveys for future use is really a procedure for which no agreement or no documented permission or agreement from the subject would be required outside of the research context. You’re asking subjects to agree to store their data in a repository for future use, for the foreseeable future, for whatever purpose without any written documentation from the subject that they’ve agreed to this. This is where things get a little dicey and we’re going to see this a lot under the new revised Common Rule when it comes to things like broad consent and all of that. And so we left you all with hmmm. This is something the IRB is really going to have to grapple with and think about. What is required here? And then when we think about HIPAA, we didn’t even mention that because we need to get to questions. But you know, under what authority would one disclose data for future studies with HIPAA if you don’t have any signed documentation from the subject. And so we don’t have an answer for this one. These are the types of issues and things the IRB has to consider. The takeaway here is it’s not always black and white. There’s a lot of gray in all of these decisions.

**Dr. Karen Jeans:** Yeah this is Karen. There’s a lot of different questions that need to be asked here. For example, when we’re talking about future use. Is it future use of identifiable data? Is it de-identified? Is it staying within the VA? Is it outside the VA? So that’s why this is one of those where there’s a lot of other questions that need to be asked to really figure out whether or not subjects are being informed about what the intent of the research is and what they’re agreeing to basically.

**Soundia:** And whether we would need some documentation from the subjects in the future to justify use going forward for future use.

All right, Heidi. This was a long one. Here are the references. We can get to some of the questions. Some of the questions we may have answered already but if we do we we’ll just say we’re going to pass on that one because it’s already been covered.

**Heidi:** Okay. Sounds good. So we will get started on those questions. I’m just going to start at the top and work my way down. And just one quick note to the audience, when you’re sending questions in please note I am not a subject expert. If you’re sending in acronyms, if you’re sending in abbreviations I typically have no idea what you’re talking about and I’m relaying the questions here so please do your best to make it easy as possible for me. The first question here can the PO clarify the following statement in VHA 1605.01 page 37. I know you guys can read it on your screen. The facility privacy officer is responsible for redoing the HIPAA authorizations to ensure legal authority exists prior to the use, access, collection, creation, and disclosure of PHI obtained orally in writing by research investigators since this implies there may be instances where oral HIPAA authorization would be possible i.e., alterations to remove signature and date requirement.

**Soundia:** I think we’re going to, in the interest of time and the fact that it’s such a long question, I think we’re going to ask that individual to please send it to privacy. In all honesty we’d have to re-read the question a few times to make sure we were able to convey it correctly so let’s have that one go to privacy.

**Dr. Karen Jeans:** Yeah as Kim had referenced earlier, there is no alteration to the signature and date for the authorization.

**Heidi:** Okay. The next question I have here. Can you provide an example of an alteration of HIPAA?

**Soundia:** It’s a great question. Kim, by any chance, do you have some examples that you’ve seen where it’s been useful to request an alteration of HIPAA?

**Kimberly:** In all honesty, the word alteration, I wish we could actually remove that from the definition because there’s not a lot of alterations, there’s not a lot of fluidity in reference to what the actual authorization requirements are. They are very distinct and they’re indicated in 1605.01. So whatever’s indicated in that document cannot be altered. It has to be present. So if it’s something in 1605.01, any authorization that you don’t want to actually secure then your best bet is to request a waiver of authorization.

**Soundia:** Thank you, Kim.

**Dr. Karen Jeans:** Thank you, Kim.

**Heidi:** The next question I have here. Is HIPAA and consent needed for an acceptability survey of providers for an intervention that is deemed as operational QI by an IRB?

**Soundia:** If something is deemed QI by an IRB then we’re not in the realm of research. So we wouldn’t be looking at informed consent at least. If we’re talking about QI activities and, I’m presuming accessing records for QI activities, are there any HIPAA authorizations that would be required? I don’t know if there’s an exception. Kim, is there an exception for accessing PHI for QI activities?

**Kimberly:** That actually falls into the healthcare operations arm of HIPAA and so there’s no requirement for an authorization.

**Soundia:** Excellent. Thank you.

**Heidi:** Okay the next question I have here. If a provider might be disclosing PHI of another, for example, a patient, is HIPAA triggered?

**Dr. Karen Jeans:** So this is Karen. Yes. I think it’s important to, are we talking about disclosing PHI for research purposes, or are we doing it for clinical purposes? Because again, under HIPAA, HIPAA’s going to be triggered if we’re under the covered entity. So if we’re conveying, you know, for collecting, using, if we’re a clinician, we’re, you know, we are disclosing PHI of another patient. You can’t do that for non-research purposes. Excuse me, I’ve got this reversed. For research purposes you need either a written HIPAA authorization or a waiver of HIPAA authorization. If it’s not research, it falls under treatment, payment, healthcare operations. So yes, so VA we’re a covered entity so it will fall under us and then I’m going to fall under Kim right now as well because.

**Kimberly:** Right. The [unintelligible 1:39] simplicity and the most simplistic way to look at it is that you have to ask VA or the actual individual. So you’re asking permission to utilize their data. So you either ask that permission via securing an actual authorization from the individual supplying the information, or you submit a request to the IRB. And once you’re actually granted permission, then you can actually access it. But you have to request permission from the actual owner of the data which is VA or it’s the individual supplying the data.

**Heidi:** Okay. Thank you. The next question that I have here. To clarify that I heard correctly, did Kim say that VA considers a combination of health information plus only demographic information, for example; gender, age group, etc., none of the 18 HIPAA identifiers to meet the HIPAA definition of PHI?

**Kimberly:** That is incorrect. Any information collected on a Veteran, any information, demographic or otherwise, that is stored in a VHA system of records is considered protected health information. In reference to an actual HIPAA identifier, they may be different. Like you could have situations where gender is not an actual HIPAA identifier but the gender and the association with the Veteran makes it protected health information.

**Soundia:** Thank you, Kim.

**Heidi:** Thank you. The next question I have here. Can you explain again who can and cannot sign the HIPAA authorization and ICF?

[unintelligible 1:41:18]

**Kimberly:** And I’m sorry Karen if I preempted you. The individual who can sign the HIPAA authorization would be the individual participant themselves or their actual personal representative.

**Dr. Karen Jeans:** And for the consent form it’s the subject or their LAR. And the LAR might be the personal representative but it could also be a number of other individuals and you kind of go down the list, depending on whose available.

**Soundia:** Thank you.

**Heidi:** The next question that I have here. Is there a VA form equivalent to 10-0493 authorization for non-Veterans?

**Dr. Karen Jeans:** So this is Karen. If it’s VA research it doesn’t matter whether or not it’s for non-Veterans or Veterans. If they’re a VA subject and written authorization is required, the 10-0493 must be used.

**Heidi:** Thank you. The next question here. So if the Veteran has an LAR, but no legal PR, can they or can’t they be in the study? The LAR signs the ICF but who signs the HIPAA?

**Soundia:** Kim can you chime in on that one? I remember you said it has to do with the level of capacity. Whether they’re fully incapacitated or not that the PR is triggered once they’re fully incapacitated but what if they’re somewhere in-between?

**Kimberly:** If they’re somewhere in-between then the individual participant would actually have to sign the authorization. If they’ve been deemed fully incapacitated then the personal representative does. Because those are the only two individuals, either the individual or the personal representative acting as an agent can sign for the actual participant. There’s a lot of, in situations like that, there’s a lot of, the responses would be it depends. It depends. It’s almost situational. So you’d actually, these are the kind of one-offs that you’d actually need to consult with your privacy officer on.

**Dr. Karen Jeans:** And keep in mind we’re focusing on capacity. You know if the question was asking about whether they can actually make the mark or make the signature there are allowances for someone who can’t make the mark to still somehow indicate, right, their consent for both the HIPAA and the consent form. The PR comes in when we’re talking about capacity, and the LAR for capacity.

**Soundia:** Thank you.

**Heidi:** The next question that I have here, I understand the IRB can waive documentation of informed consent but can they also waive documentation of HIPAA authorization?

**Soundia:** Right. And we’ve talked about that already. It’s a core element. If you can’t get documentation of HIPAA, for whatever reason, this is where you ask the IRB for a complete waiver of HIPAA. Thank you.

**Heidi:**  Okay. The next question here, in case one you say that no data leaves the VA. But if a smart phone app is being used, isn’t there a possibility that there is data outside of the VA depending upon what the app might be doing or collecting? How do we deal with such issues from a privacy and information security perspective?

**Dr. Karen Jeans:** So this is Karen. I’ll start in on this. You are correct. For purposes of the case example it was, that’s exactly why it was specifically specified that no data would leave the VA. This was a smart app that was developed within the system and it would go on the server. However there are indeed, again, many apps that we utilize in VA in which the data will be located outside the VA. It will go to the server before it comes back to the VA and that’s where we need to know whether or not that information is sensitive. Whether or not it is, you know, protected health information. When does it become VA data? That’s a key question here? So in terms of the privacy issues, that’s what we have to address first and also human subject relation issues in terms of information security. This is where, again, the different scenarios drive it with the information security officers depending on what the system is. Many times in some of the commercial apps we’ve been using for mobile apps, we enter into agreements regarding the use of this including one big issue on this is when the mobile app company, whoever’s sponsoring it, we have to put on restrictions on their use of the data. We had one recently where there was a clause in there if one hadn’t read it, where the company owned the data that was on their server after 10 years and so the specific’s drive it. I know that’s not, it doesn’t fit all situations so we do have to find out first when does it become VA data? What is the authority for that data? Is it the PII? And we will get the different information security issues related to it depending upon the different vendors. So that’s when we work directly with our information security officers.

**Heidi:** Okay. Thank you. The next question I have here. In a chart review study, is there an acceptable number of medical records where it would not be practical to get consent or HIPAA. For example, what if the researcher wanted to look at the charts of 50 Veterans at their medical center. Should they be given a waiver or should they seek consent from each Veteran since 50 is not that many?

**Soundia:** Right. No. It’s not about numbers. That’s a good question but no it’s not about numbers. It’s really going to be about the whole study. And the IRB is going to take into account what’s being accessed, whether it really is an issue of impracticability, whether it’s worth, you know, reaching out to the subjects and asking them to access their data when nothing else is going to be asked from the subject, the nature of the information that’s being requested from their medical records, all of those things. But numbers don’t necessarily drive a decision of when to seek consent versus when to ask for a waiver.

**Heidi:** Thank you. The next question I have here. In case study two, if the survey is sent to 2000 people and no phone call is made and information about the study are included on a cover sheet, could a waiver of informed consent be granted? It could be impracticable to call that many people.

**Soundia:** So two things now. You asked if a waiver of informed consent could be granted. If you’re sending out a survey by mail, you wouldn’t necessarily need to ask for waiver of consent. Remember consent’s the process. So consent is the process of informing subjects about what is being done. I think what you’re asking really, then, is do we need to obtain the documented consent? But consent can be done by informing subjects, sending an information sheet that has all the information about why are we conducting this study, how will the information be used. So you wouldn’t necessarily need to request a waiver of consent if you’re sending out the survey.

**Dr. Karen Jeans:** And remember, we’re obtaining a waiver of documentation of informed consent. And this is where I absolutely agree with Soundia, that I hate the use the word verbal.

**Soundia:** It messes me up.

**Dr. Karen Jeans:** Because a lot of times we use a waiver of documentation of informed consent by sending that information sheet with the survey and there is truly no phone, there’s no oral conversation at all and so that is the waiver of documentation of informed consent. The returned survey is the indication they consented.

**Soundia:** That’s a good question.

**Dr. Karen Jeans:** Excellent. Thank you.

**Heidi:** The next question we have here. We often have a respondent click the check box on their survey to agree to have their data stored for future use. While this is not a signed consent form, it is a form of documentation. We request a waiver of documentation for this but from the last scenario, it seems like this might be considered documentation of consent. Please clarify.

**Soundia:** So I think that this could get tricky because what you didn’t talk about was HIPAA. By signing a check box saying that they agree to something in an electronic format, that is indeed, you know, if I already approved waiver of documentation of consent, they don’t necessarily need to even sign anything but you could. Is that correct?

**Dr. Karen Jeans:** Yes. Yes. In terms of like they can only do an X. The Common Rule is specific about signature. VA is specific about signature and date. So a check box is not a signature.

**Soundia:** But it’s IRB approved, waiver of documentation of consent.

**Dr. Karen Jeans:** Documentation.

**Soundia:** And you use a check box, you could use a check box but that’s not going to be a signature. The IRB said you don’t need a signature.

**Dr. Karen Jeans:** So the last scenario Soundia was talking about, again, that’s why she said it’s tricky, there’s no policy, Common Rule, VA that says that written consent is required for a repository for databases, or vial specimens for that matter. Which again, you have to think about the human subject protection component. Again, we’re not staring at HIPAA right now. We’re talking about what is being asked of the subjects and whether or not you should be obtaining a written informed consent. Whether or not you can do it with a waiver of documentation of informed consent, especially when we’re dealing with repositories and the accountability that takes place with that. It is substantial. So you have to think of not only the collection, but also the storage and the distribution and the ability of the subject to withdraw.

**Soundia:**  And also going forward when you want to reuse that data in another IRB or someone comes and says well what’s the basis? How do we know that consent was obtained? Do you have something that you can, yes, rely on?

**Dr. Karen Jeans:** So there’s a lot of issues in this.

**Soundia:** Heidi. I don’t how many questions we have left. I know we’re over time.

**Heidi:** We’re about a half hour over time. We’re about a half hour of time. I have to log off. We have about 10 pending questions.

**Soundia:** Well I think we’re supposed to end at 3:45. That was our scheduled time for the lecture.

**Heidi:** The PRIDE sessions are actually scheduled from 2:00 until 3:30.

**Soundia:** Okay. Well then let’s go ahead and end then. Okay?

**Heidi:** Okay.

**Soundia:** We would like to thank everybody for participating. I’m sorry for the confusion. We thought we had blocked out until 3:45. If you have additional questions, please send it to the regulatory mailbox and then we will go from there. And then also, at the end, you’re going to see a survey pop up so please complete that survey. We’re going to take into consideration always any advice and suggestions for improvement because we can always continue to improve. And we hope you found this useful and thank you so much for your time and thank you.

[END OF AUDIO]