ORPP&E Webinars

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Session: Revised Common Rule: Changes to Exempt Categories and Limited IRB Review

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**Dr. Kristina Borror:** Hello there and welcome to today’s webinar. Today’s sessions is on the Revised Common Rule: Changes to Exempt Categories and Limited IRB Review. A copy of today’s handout was sent by email but you can also find a copy in the dashboard under handouts. We will be recording this webinar and a link to the recording will be sent to you by email after the webinar. The audio for the webinar is through your computer, however, if you’re having trouble with the computer audio, you can switch to phone audio. There is dial in information on the email that you were sent and also you can go to the audio tab on the dashboard and select phone call and the dial in information will be displayed. We are in lecture mode so all attendees are muted. You will have the opportunity to submit text questions by typing your questions into the questions pane of the control panel. You may send in your questions at any time during the presentation but we will collect these and address them during the Q&A session at the end of today’s presentation. I have with me on our webinar today, both Petrice Longenecker and Karen Jeans and Soundia Duche from ORD so they can help if there’s any questions that I can’t answer or if they have anything to add to anything that I’m saying.

So we’re talking today about the Revised Common Rule, changes to exempt categories and we’re also going to talk a little bit about limited IRB review. So I’m going to give you a little bit of background and some of this is going to be stuff that you’ve heard from Soundia and others even as recently as yesterday. But we’re going to go into a little bit more detail on the exemptions and this part B applicability, the changes to the exemptions, limited IRB review, and then we’ll touch a little bit on broad consent. And certainly it doesn’t hurt to go over these things multiple times. I know that sometimes it takes a few times to get it into your brain.

So a little bit of background about the revised final rule. As you know, the current regulations for the protection of human research subjects were revised and that revision was published in January of 2017 in the federal register. For VA the Common Rule is codified at 38CFR16. And the changes to the Common Rule were really intended to modernize the system of oversight for research involving human subjects and also to make it more effective. And those rules had been in place since 1991 with, really, very minor changes. And there has been a delay of the general compliance date until January 21st, 2019. And Soundia talked about that in a fair amount of detail and we’ll go into just a little bit of detail but not too much. So some of the key dates and time periods for the transition: The effective date for the 2018 requirements has been changed to July 19th, 2018. And although the July 19th is the effective date of the rule, the pre-2018 requirements, that is the current Common Rule, must be followed until January 21st, 2019, except for some few burden reducing provisions that I’ll go into a fair amount of detail. And just to clarify some of the terminology, when I talk about the final rule or the Revised Common Rule or the 2018 requirements these are all synonymous and the compliance date is January 21st, 2019. When I’m talking about the current regulations, I sometimes may refer to them as the pre-2018 requirements.

So starting July 19th, 2018, through January 20th of 2019, this is the period of time that institutions can take advantage of burden reducing provisions of the 2018 requirement. And general research that is conducted during this time period has to follow the current rule or the pre-2018 requirements. But there’s been an allowance to implement some burden reducing provisions and those are the revised definition of research, which deems certain activities not to be research, the allowing for no annual continuing review of certain categories of research, and the elimination of the requirement that IRBs review grant applications or other funding proposals related to the research. And note that VA may only apply two of those provisions; that is the revised definition of research and the elimination of review of the grant application. And this period is often referred to as the delay period between July 19th, 2018, and January 20th, 2019. And as I mentioned, the general compliance date is January 21st of 2019 and basically any research that is started or approved or determined to be exempt on January 21st, 2019, or after that date, has to follow the 2018 requirements, that is the Revised Common Rule. The compliance date for the cooperative research provision, which is the single IRB review requirement for multi-center research, doesn’t go into effect until January 20th, 2020.

So just a little bit about some of the changes to the exemptions. This is just an overview. All but one category was revised and some new categories were added including one that was replaced. And there’s two new processes that were introduced with the new categories including limited IRB review and broad consent.

Now there are certain subparts to the Common Rule and they involve research involving special populations and the exemptions may apply differently to research that is subject to those subparts.

So subpart B, which is for research involving pregnant women, human fetuses, and neonates involved in research, the exemptions are consistent with the pre-2018 rule. That is that any research that applies to subpart B or research involving pregnant women, human fetuses, and neonates can be applied, the exemptions can be applied to that. And you should also check out VA handbook 1200.05.

For research involving prisoners which is under sub-part C. The final rule actually changes the pre-2018 rule. The pre-2018 rule basically said you couldn’t use the exemptions for research involving prisoners, but under the 2018, or the revised final rule, there is an allowance if the research involves a broader subject population that only incidentally involves prisoners. The exemptions can be applied to that. And also it permits the exemption of secondary research involving either information or biospecimens from subjects that are prisoners if that research is not actually examining prisoners as a sub-population. And the final rule also allows if you have research that is exempt and somebody becomes a prisoner during the study, it allows the subjects to continue in that exempt research and you should check out VA Handbook 1200.05 section 18 for research involving prisoners.

As far as sub-part D, this is for research involving children. And the final rule doesn’t permit the use of the exemptions if the research involves children and also benign behavioral interventions or if the research involves educational tests and sensitive identifiable information is recorded. Also, which is the same as the current or pre-2018 rule, observation of public behavior for research involving children under category two is allowed only if the investigator doesn’t participate in the activities being observed. And you cannot exempt survey and interview procedures with children and that is the same as the current pre-2018 rule. And the requirements are found under 1200.05 section 19 in the VA Handbook.

So here’s just a little summary of the changes to the exemptions. A general difference from the pre-2018 rule is that some of the exemptions have been expanded. New exemptions have been added and these allow investigators to retain identifiable information that might be sensitive, which previously was not allowed to be exempt. But this requirement, in order to do that, there’s a requirement that specifies privacy and confidentiality protections are satisfied. And the changes are also intended to exempt more low risk social and behavioral research.

So what do we mean when we say that a study is exempt? Generally it means that the research isn’t subject to the requirements of the Common Rule. And the, you know, it’s important to note that exempt doesn’t mean that all research that is exempt is exempt from all of the requirements of the Common Rule. And as you will note that there are going to be some new requirements for, as I mentioned as Soundia discussed yesterday, that some have new requirements, for instance, broad consent or for limited IRB review. And these proposed changes really are intended to align better with the ordering in the Common Rule and these new exempt categories are based on their risk profile. And the Revised Common Rule does not include a proposed requirement that was in the notice of proposed rulemaking that exempt determinations have to be made in specific ways. And it doesn’t include the use of an exemption decision tool as was proposed, but this doesn’t preclude agencies from developing a decision tool in the future.

So there is a new regulatory section. Previously in the pre-2018 rule, there were six exemptions and they were in section 16.101(b). In the Revised Common Rule they are in section 104 and there are now eight categories of exemptions.

This section 104 was previously reserved in the pre-2018 rule. It didn’t actually have anything in there. And now 104 is the exempt research section. And 104(a) talks about the requirement that activities have to comply with the requirements of the section in order to be exempt. And so, as I said, some of those requirements may include some limited IRB review or some broad consent. Section (b) talks about the use of the exemptions for special populations, which we already discussed, including pregnant women, prisoners, and children. Section 104(c) is currently reserved in the Revised Rule and section D actually has the eight categories of exempt research. And will go over those each in turn in a fair amount of detail now.

So category one is Research in Established or Commonly Accepted Educational Settings and it involved that kind of research in the pre-2018 rule. But there has been a change now and this research now has a condition that the research will not likely have adverse impacts on either students learning required educational content or assessing educators who provide that instruction. And it requires that the research only include normal educational practices. And that can include regular and special educational instruction strategies, research on the effectiveness of or comparison among instructional techniques, curricula or classroom management methods.

So now we have our first poll. So first I’m going to read the question and the answers and then after we’ve had a chance to look at these, we’re going to pull up the poll because the poll is sort of in shorthand. So the question is exemption category one has been amended from the pre-2018 rule to include a condition that the research is not likely to have adverse impacts on, and more than one answer may be appropriate; students’ time in the classroom, students learning required educational content, teacher to student ratios, and assessment of educators who provide instruction.

So I’m going to ask Petrice to bring up the poll so that folks can start entering their answers.

**Dr. Petrice Longenecker:** So we’re collecting responses and you let me know, Kristina, when you think it’s been enough time and I’ll go ahead and close and share.

**Dr. Kristina Borror:** All righty [sic]. Okay. It’s starting to slow down so why don’t we close the poll and you can share the responses. So we can see that 80% of you said students learning required educational content. And 63% said assessment of educators who provide instruction. 28% said students time in the classroom. And 17% said teacher to student ratios. So we’re going to hide those poll results and we’ll go ahead and look and see what the correct answer is.

And the answer’s are student’s learning required educational content and assessment of educators to provide instruction. And any research that wants to use exemption one cannot adversely impact those two things.

So we have another poll question. And this question is a study team wants to test whether adding an hour of physical education, or PE, per week reduces disciplinary actions for student behavior. In half of the schools in a district, students will have an additional hour of PE each week which will occur in place of one hour of their regular science instruction. Would this study meet the criteria for the revised exemption one? Yes or no. So I’m going to ask Petrice to pull up this poll about this research and whether or not it will meet the requirements of exemption one. Okay. So it’s slowing down so why don’t we stop the poll and we’re sharing the results. And 78% said that no, this research involving replacing some science instruction with physical education would not meet the requirements of exemption one and 22% said it would. And we will go to the answer.

And the answer is that the study would not meet the criteria for exemption one because research would occur in place of one hour of the regular science instruction. And remember there is a prohibition of having the research activities have adverse impacts on the students learning required educational content which would likely happen if you took away some of their science education.

So next let’s talk about category two. And this is for research that only includes interactions involving educational tasks, and that includes cognitive diagnostic aptitude or achievement tests, also survey procedures, interview procedures, or observation of public behavior. And there are three criteria that can be met to meet this exemption. One is that the information obtained is recorded in a way that the identity of the subjects can’t be readily ascertained by the investigators either directly or through identifiers. Or any disclosure of the subjects responses outside the research couldn’t reasonably place those subjects at risk, for instance, of criminal or civil liability or hurt their financial standing or employability. And there’s a new third option and that is that the information can be identifiable but the IRB has to conduct a limited IRB review and make the determinations required under 111(a)(7) and that is the provisions for protecting privacy and maintaining confidentiality. So the first two should look familiar. They were very similar, if not identical, to the criteria for exemption two in the pre-2018 or current rule, but this new third criteria is a new flexibility. And the final rule mentions that research in this category can include visual or auditory recording as research methods. And these surveys can’t be combined with any collection of biospecimens and they also can’t be combined with any interventions because that would not qualify for exemption under this category. And as I mentioned that category two doesn’t allow research on surveys or interviews with children or children being observed if the investigator participates in the activities being observed. But if you’re observing children who are having public behavior where there’s no intervention by the investigator, that would be allowed to be exempt under exemption two.

So another poll question. So under the Revised Common Rule, limited IRB review is required for exemption of research that only includes interactions involving educational tests, survey procedures, interview procedures or observation of public behavior if, and check all that apply. So more than one answer could be correct. And the first one is the information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained either directly or through identifiers. The second choice is any disclosure of the human subjects responses outside of the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subject’s financial standing, employability, or educational advancement or reputation. And choice number three is that the information obtained is recorded by the investigators in such a manner that the identity of the human subjects can readily be ascertained directly through the identifiers link to the subjects and responses could put subjects at risk. So which of these three categories of research require the IRB to conduct a limited IRB review? And so we’ll bring up the poll now. Okay. It’s starting to slow down so why don’t we close the poll and share the results. So 62% said that limited IRB review is required if the information is risky and it’s recorded in such a manner that the investigators can readily ascertain who the information is from. 56% said that limited IRB review is required if disclosures of the subject’s response could place the subjects at risk. And 31% said that if the information is recorded in such a manner that the identity of the subjects cannot be readily ascertained. So which of these require limited IRB review? So let’s hide the results and let’s go to the answer.

And the answer is that limited IRB review under this exemption is required if the information obtained is recorded by the investigator such that the identity can be readily ascertained either directly or through identifiers and the responses could put the subjects at risk of some kind of harm. So remember the first two, the ones where you’re recording things so that they can’t be ascertained or if the information could not put them at risk, you don’t require limited IRB review right? So there’s no requirement for limited IRB review. But if you are recording and they can put the subject at risk, then it’s now exempt under the 2018 requirements. But to add some extra protections to this kind of research that could be risky, then this requires a limited IRB review and the IRB needs to look at those privacy and confidentiality protections.

So let’s go to the next exemption. So exemption three has been changed. So the exemption three from the pre-2018 rule has been removed and this was research that was involving educational test survey procedures or observational public behavior for elected or appointed public officials or folks who were candidates for public office or in cases where there was a requirement without exception by a federal statute for confidentiality protections. And so the idea is that if the purpose of this activity is to hold a public official or a candidate up for public scrutiny and not keep that information confidential, such an activity would not be considered research. It would probably meet the category of scholarly and journalistic activities that has been sort of carved out of the definition under the revised rule. If that kind of activity or research would be research, then it would likely be exempt under the new exemption two. If they were going to record identifiers, it would have to be kept confidential and very little of such type of research is supported by the VA.

So what replaced exemption three? This new category is for research involving benign behavioral interventions. And this can be in conjunction with collection of information from subjects but they have to be adult subjects and it does allow audio visual recording and the subject has to prospectively agree to the intervention and the information collection. And the benign behavioral interventions, here’s the definition. So basically it couldn’t put the subjects at any physical or long lasting impact. They have to be brief, harmless, painless, not invasive. And you know, the researcher has to not have any reason to think that the subjects would find the interventions offensive or embarrassing. And the regulations give an example of having subjects solve puzzles under various noise conditions. And as I said, this only applies for research with adults. It’s not applicable to research involving children.

So there are some criteria that have to be met in order to use this exemption. At least one of these criteria have to be met. One is that the information is recorded by the investigator in a way that the identity of the subjects can’t be ascertained either directly or through identifiers. That sounds familiar, right? We saw that in exemption two. Or any disclosure of the subject’s responses wouldn’t put them at risk. We also saw that in exemption two so these should look familiar. And there’s a third one that if the information is recorded in a way that the identity of the subjects can be ascertained and ostensibly, this is if the research could put them at some kind of risk, that the IRB conducts a limited IRB review to make determinations required under 111(a)(7). And remember these are the provisions to ensure that the privacy of subjects and confidentiality of data are adequately maintained. So these criteria sound very similar to the ones we saw in exemption two.

And this third one is new, you know, it allows some extra risk as long as this new limited IRB review occurs. And if this research involving benign behavioral interventions involves deceiving the subjects about either the nature or the purposes of the research, it doesn’t apply to this exemption unless the subject actually authorizes the deception. And the way they do that is through prospectively agreeing to participate in research in which they’re told that look, you’re not going to be aware of all of the nature or purposes of the research or you’re going to be misled about some of those things. This is sometimes referred to as authorized deception. And an example of this might be if you told the subjects for scientific reasons this consent form does not include complete information about the study hypotheses and the research questions being tested but you will be fully debriefed following your participation in the research. That’s sort of an example of this kind of concept of authorized deception.

So we have another poll question. I’m going to read it first. It says, under the Revised Common Rule, research involving benign behavioral interventions is never exempt if the information obtained is identifiable and any disclosure of the human subjects’ responses outside the research would place the subjects at risk. So this would never be exempt, true or false? So I’m going to ask Petrice to bring up the poll. Okay it’s slowing down so why don’t we close the poll, Petrice, and if you could share those results. And wow, I’m surprised that this is so close; 53% said true that under the Common Rule for research involving benign behavioral interventions is never exempt if the information obtained is identifiable and disclosure could put the subjects at risk. And 47% of you said that that was false.

Okay so let’s hide those results and we’ll go and see what the answer is. The answer is actually is false. So if the information is identifiable and the disclosure of the responses could put them at risk, remember it can be exempt if the IRB conducts a limited IRB review and looks at the provisions for protecting the privacy of subjects and the confidentiality of data and determines that they are adequate. So that’s a flexibility that we saw in exemption two and it’s also present in exemption three.

Okay so we have another question about exemption three on the next slide. I’m going to read it first. Under the Revised Common Rule, research involving benign behavioral interventions, again, is not exempt if the research involves deceiving the subjects regarding the nature or purposes of the research, unless the subject will be provided with additional pertinent information after participation. The researcher does not record any identifiers. The subject is prospectively informed that he or she will be unaware of or misled regarding the nature or purposes of the research. Or the subject is an adult. I’m going to ask Petrice to share the poll and provide the answers that you think are correct. Okay the responses are slowing down so why don’t we close the poll and share the answers. So 79% of you said that the subject is prospectively informed that he or she will be unaware of or misled about the nature of the purposes of the research. 36% said that the subject will be provided with additional pertinent information after participation. 37% said the subject is an adult. And 16% said the research does not record any identifiers.

So let’s hide those results and let’s see what the answer is. And the answer is, under the Revised Common Rule, research involving benign behavioral interventions is not exempt if the subject is not prospectively informed that he or she will be unaware of or misled. If the research involves deceiving the subjects about the nature and purposes of the research, unless the subject is prospectively informed that he or she will be unaware of or misled regarding the nature or purposes of the research the research cannot be exempt. So a lot of you thought that the answer might be that they’ll be provided with additional pertinent information after participation and I think that you might be remembering that from the waiver criteria. So that’s one of the waiver criteria that if you want to waive or alter informed consent, but that is not a criteria for doing deception in exemption one. And some of you did, a lot of you did select that the subject is an adult. And it is true that you can’t do exemption three unless the subject is an adult but that’s not, that’s not the main reason why. This was about whether or not you could deceive the subjects about the nature or purposes of the research and what is the criteria for that.

So the next exemption is category four and this category was revised in the Revised Common Rule and this is related to secondary research for which consent is not required. And this is secondary research uses of identifiable private information or identifiable biospecimens and at least one of four possible criteria have to be met. And unlike the previous, current, pre-2018 rule which said that the data has to be existing at the time the research was proposed, under the Revised Common Rule category four, they do not have to be existing at the time the research is proposed. So data can be collected prospectively and still be used for exempt research under the final rule.

And a little bit more about category four. As I said, at least one of four criteria have to be met in order for this secondary research to be exempt under category four. The first one is that the information or biospecimens that are individually identifiable are publicly available. The second one is that the information is recorded by the investigators in a way that subjects identity cannot be ascertained by the investigator either directly or indirectly. And the investigator does not contact subjects and will not re-identify the subjects.

And there’s a third criterion that the research only involves information collection and analysis involving investigators use of identifiable health information and that use is regulated under the privacy rule for the purposes of healthcare operations or research or for public health activities and purposes. And the fourth criterion is that the research is conducted by, or on behalf of, a federal department or agency and it uses government generated or collected information. And this information has to have been obtained for non-research purposes and there have to be a particular federal privacy standards that protect that information. So those are the four possible criteria for exemption four. And the fourth, whoops, let’s go back up here. This fourth provision has limited applicability to federal researchers and those that are conducting studies on behalf of the federal government such as contractors but that could apply to VA researchers. And the HIPAA exemption, this number three, is limited to studies where the investigators use is protected under the HIPAA rules.

So let's go to another poll question and this is, under the Revised Common Rule secondary research uses of identifiable private information or identifiable biospecimens is exempt only if the information is existing at the time the research is proposed, true or false? I’m going to ask Petrice to share the poll and you can start answering that. And the responses are slowing down so let’s close the poll. And if you could share that. So 72% of you said that it’s false that under the Revised Common Rule secondary research uses of private information or identifiable biospecimens are exempt only if the information is existing at the time of the research as proposed. And 28% said it was true.

Okay so let’s hide those responses and let’s see what the answer is. And the answer is that it is false. So this exemption now actually allows research involving identifiable private information and biospecimens that are not existing at the time of the research is proposed in order to be exempt under exemption four.

So let’s do another question about exemption four. Okay. And this one is about secondary research use of identifiable private information or identifiable biospecimens for which consent is not required and if it is exempt. And you are to check all of the ones that apply. And there may be more than one answer. And the first one is investigator’s use is regulated under HIPAA as “health care operations,” “research,” or “public health.” The second one is research is conducted outside of the United States. Number three is research involves no greater than minimal risk. And number four is research is conducted by, or on behalf of, a federal agency with data collected or generated by the government for non-research purposes, and the information is protected by federal privacy standards. So I’m going to ask Petrice to share the poll so that you can select the answers that you think are correct and more than one answer may be correct. Okay so things are slowing down. We can close the poll and share the results. So 79% of you said that the investigators use is regulated under HIPAA or “health care operations,” “research,” or “public health.” That it could be exempt under this exemption. 75% said it would be exempt if research is conducted on behalf of a federal agency using data collected or generated by the government for non-research purposes and there’s federal privacy protections. And 40% said the research involves no greater than minimal risk. And 6% said the research is conducted outside of the United States.

Okay so let's hide those responses and see what the answer is. And the answer is there are two of those that were exempt under exemption four. And that’s secondary research use of identifiable private information or identifiable biospecimens if the investigator’s use is regulated under HIPAA as “health care operations,” “research,” or “public health.” Or it is basically federal research with federal data and there are federal privacy protections. So some of you thought that maybe it has something to do with the research being conducted outside of the United States and that wasn’t correct. And that the research involves no greater than minimal risk. And you may have been confusing that with some of the current expedited standards.

So let’s talk now about exemption category five. And this is for certain research and demonstration projects and this has been expanded so it now applies to federally supported research. Previously it had been limited to just federally conducted research. So this could be, actually, research that is funded by a federal agency instead of just done by a federal agency. And the research has to be designed to study, evaluate, and prove, or otherwise examine public benefit or service programs. And it clarifies the components that the exempt research has to be subject to approval for and this can be delegated to subordinate agencies.

And the new exemption category five [unintelligible 48:42] to of what this might look like and these include procedures for obtaining benefits or services under these programs or possible changes or alternatives to the programs or procedures or changes and methods or levels of payment in order to receive benefits under these programs. And there is a new requirement that if any federal agency that conducts or supports research and they want it to be exempt under this category five, they have to publish a list of all the research and demonstration projects that are being approved under this provision. And these projects have to be published on the list prior to starting the research involving human subjects if it wants to be exempt under this exemption.

Next is category six. And this is taste and food quality evaluation and consumer acceptance studies. And this is only if wholesome foods are used and there’s no additives or if a food is consumed that does have, it has a food ingredient at or below the level and a use that is found to be safe or any chemical or environmental contaminate below the level found to be safe by the FDA, EPA, or the U.S. Department of Agriculture. And this is the only category that remains unchanged in the Revised Common Rule.

So next we go into the two completely new categories. These categories do not have any complimentary or similar category in the pre-2018 rules. They are completely new and they both relate to identifiable private information and biospecimens. And category seven is for storage or maintenance for secondary research use of these identifiable private information or identifiable biospecimens and broad consent is required. And this is only exempt if the IRB conducts a limited IRB review. So remember we saw limited IRB review before for a couple of the other exemptions, for exemptions two and three, under certain circumstances. And in this case, category seven always requires this limited IRB review. And in this case, they’re looking at the privacy and confidentiality protections to make sure that they are adequate and also to make sure that broad consent is obtained and appropriately documented. So this kind of exemption would be used if an investigator wants to store information in a research data bank or store biospecimens from a pathology lab in a research repository, they could use this exemption if all the conditions of the exemption were met. And it can be used in conjunction with exemption eight, actually use that stored information or biospecimens in secondary research and we’ll talk about that later.

But first we’re going to do a quiz question. And this question is exemption category seven may be used for research involving secondary use of identifiable biospecimens and identifiable private information, true or false? I’m going to ask Petrice to share the poll so you can answer whether or not you think it’s true that exempt category seven may be used for research involving secondary use of identifiable biospecimens and identifiable private information, or is that false? Okay things are slowing down so why don’t we close the poll and share the results. So 68% said true, that category exemption seven can be used for research involving secondary use of identifiable biospecimens and identifiable private information, and 32% of you said false.

Well I’m surprised at how many of you got this one wrong. And it’s false and that’s because category seven is only for storage and maintenance of identifiable biospecimens and identifiable private information. And that’s before the secondary use and analysis of that information or biospecimens, okay?

Now let’s talk about exemption eight. This is the one that involves secondary use of this identifiable private information or identifiable biospecimens. And so broad consent is required. So the criteria for using category eight for this secondary research use is that you did get broad consent for using this information. And this was documented, this broad consent was documented, or a waiver of documentation was obtained. And the IRB has to conduct a limited IRB review and they have to determine that the privacy and confidentiality protections are in place under 111(a)(7) and also determine that the use of these biospecimens or information is actually within the scope of the broad consent. And limited IRB review is always required for this category as it is for category seven.

And there’s also a requirement that the research does not include returning individual research results to subjects. And that doesn’t prevent, if returning results is required by law, that doesn’t prevent investigators from doing that. But it can’t be part of the research plan otherwise. And if an investigator wants to use information or biospecimens that are in a databank or in a pathology lab or in a research repository, they could use this exemption assuming all other relevant conditions of the exemption are met. And this can be used in conjunction with exemption seven. Remember that was the exemption for storage and maintenance of identifiable biospecimens or identifiable information.

Okay so we have another poll question. And I’m going to read it to you first. It says the following is required for research under exemption eight. And more than one answer may be appropriate. Broad consent must have been obtained. Broad consent must have been documented. Limited IRB review must have occurred to ensure there are adequate provisions to protect the privacy of subjects and maintain the confidentiality of data. And limited IRB review to ensure that the use is within the scope of the broad consent. So we’re going to ask Petrice to share the poll. Which of these are requirements for research involving exemption eight? And again, more than one answer may be correct. Okay things are slowing down and so why don’t we close the poll and share the results. So 79% said that broad consent must have been obtained. 77% said that limited IRB review of privacy and confidentiality protections have to be in place. 67% said limited IRB review that the scope of the research is within the scope of the broad consent. And 61% said that broad consent must have been documented.

Okay so let’s hide those results and let’s go to the answer. And the answer is that all of those are required except broad consent must have been documented. So remember that one of the criteria for using exemption eight is that broad consent was documented or it was appropriately waived. So it is possible to waive broad consent and use exemption eight. You may remember that there’s another requirement that we didn’t have as a choice on this one and that is that the investigator’s not include returning individual research results to subjects as part of the study plan except when it’s required by law.

So we’re done with the specific exemptions. And now we’re going to switch gears a little bit and talk a little bit more about this new beast, limited IRB review. So as you recall, that limited IRB review is required for four exemptions. And as Soundia noted yesterday, in limited IRB review, the IRB doesn’t have to ensure that all of the 111 approval criteria are met. It’s just a select criteria that have to be met. And the exemptions that require limited IRB review are exemption 2(iii) and, remember, those are educational tests, surveys, or interviews, or observation of public behavior if recording identifiers and those, the research responses, could put the subjects at risk. And exemption 3 (i)(C) and that’s benign behavioral interventions where, again, the investigator is recording identifiers and the subjects responses could put them at risk. And in these cases, the limited IRB review basically only has to look at one criteria of 111, and that’s 111 (a)(7), and that is making sure that they’re adequate privacy and confidentiality protections. So those are the requirements of the limited IRB review for those two exemptions.

But remember we also have seven and eight. So that’s a little more complicated. And for exemption seven, the limited IRB review has to look at broad consent that it was provided and as required under section 116(d). They have to look at the broad consent process and form. And there also has to be a limited IRB review of privacy and confidentiality considerations. Although those are only if there are changes to storage and maintenance for research purposes. I’m not sure if I mentioned that in the previous slide. So that’s for exemption seven. Remember there are other requirements for approval under 111 but these are the ones that need to be met for limited IRB review for exemption seven.

For limited IRB review for exemption eight. And remember, exemption seven was storage and maintenance of identifiable private information or identifiable biospecimens, exemption eight is research use of identifiable private information or identifiable biospecimens, secondary research use. And so there has to be a limited IRB review in this case of whether the research falls under the scope of the broad consent documentation or waiver of the documentation of the provisions occurred. Limited IRB review also has to look at the adequacy and privacy of the confidentiality safeguards. And the investigator cannot include returning individual research results to subjects as part of the study plan except when it is required by law. So those are the specific things that the IRB has to look at under exemption eight. And so this is a new concept for us that research is exempt and, yet, the IRB still has to look at it. But remember it’s not looking at all of the requirements for criteria for approval under 111 it’s only these specific things that the IRB has to look at for these exemptions.

Some other little tidbits of information about limited IRB review. The 109 actually basically says that the IRB has the authority to do this review and that if exempt research requires limited IRB review that research does not require continuing review. And section 110(b)(1)(iii) notes that when conducting limited IRB review this can be done in an expedited manner. So it doesn’t have to be the entire convened IRB that reviews these limited IRB reviews. It can be done by the IRB chair or some experienced member that the chair designated to do expedited review.

Okay. So we have another question here. And this question is limited IRB review always requires review of broad consent, true or false?. And I’m going to ask Petrice to bring up that poll. Does limited IRB review always require review of broad consent? And the responses are slowing down so why don’t we close the poll and share the results. And again, I am surprised that so many of you got this one wrong, that the responses were so close. 56% of you said false and 44% said true.

So let’s hide those results and go to the answer. And the answer is false. Limited IRB reviews for exemptions. Remember exemption 2(iii) which was for research involving certain educational tests if identifiers and risky information was being recorded. And exemption 3(1)(c) which is the exemption for benign behavioral interventions if risky information was being recorded by the investigators. That only requires review of privacy and confidentiality protections under 111(a)(7). Exemptions 2 and 3 are prospective data collections and do not required broad consent. Broad consent is only used for secondary research.

Okay so a little bit more about broad consent. We discussed this in greater detail in the previous presentation on informed consent. And Soundia talked about it a little bit yesterday too so I’m not going to spend a whole lot of time on this but it really is a new flexibility. And this is only for secondary research. And this is, I say it’s a new flexibility because the investigator still has the option of doing secondary research as they do under the current pre-2018 rule. And for research involving biospecimens and data that don’t have any identifiers, they can do that kind of research and it’s not human subjects research. There’s no IRB review required and there’s no consent required. Certain research involving coded biospecimens or data. And that is if the data or the biospecimens can’t be linked to specific individuals by the investigators either directly or through a coding system, so basically they don’t have the key to the code. In that case, it’s not human subjects research and there’s no IRB review required and there’s no consent required. Or investigators can do research with identifiable biospecimens or data. And they can go ahead and get a waiver of informed consent if it’s appropriate, or get study specific consent for that research. So these are currently options and they will continue to be options under the Revised Common Rule. But broad consent is a new alternative to these options.

And the next slide is a little bit more about that. And again, this is only applicable to research under these two new exemptions; exemption seven and eight. Seven being storage and maintenance and exemption eight being the secondary research use of identifiable private information or biospecimens. And remember this is only for secondary research use. They have to been collected either for a different research study or for non-research purposes. And the broad consent includes elements from basic and additional elements of consent and some that are unique. And the goal is actually to be meaningful informed consent even if you don’t describe all the specific research studies that are going to be done with that. Just have to provide a general description and sufficient information that a reasonable person might expect to understand what would be permitted. And if you are not going to give them specific information about specific research projects, you have to tell the research subjects that. And this actually allows future regulatory flexibilities for research use or storage and maintenance of those information or biospecimens.

So there are some caveats. If you do use broad consent, you can’t omit or alter any of the requirements under 116(d). So this is different from regular informed consent. So there’s no way to either change or say well we’re going to leave out this particular element or we’re going to alter it in some way. That’s not allowed for broad consent. And if you asked an individual to provide broad consent for future use of their biospecimens or data and they refuse to give that broad consent, you cannot waive informed consent if a researcher downstream wants to use that individuals data or biospecimens for human subjects research. And this was brought up yesterday in one of the questions. You know, how do you track that? And that’s a very good question. And this really does bring up the issue of needing to track who was asked to provide broad consent, who actually provided that consent, and who refused. And again, under the final rule, broad consent is only permissible for secondary research and no other types of research.

The next couple of slides are going to show you the elements. Soundia went over these so I’m not going to spend a whole lot of time on these. But remember that they include some of the basic elements of informed consent about risk benefits and confidentiality, some of the additional elements of informed consent. Now remember under regular informed consent, these are only required when the IRB determines they’re appropriate. And this case, they’re always required for broad consent. They relate to commercial profit, whether it will be commercial profit, the subjects are going to share in that profit, and whether or not they’re going to get research results. And then there are a whole slew of elements that are specific only to broad consent. And that includes a general description of the types of research, what information or biospecimens might be used for research down the road, the time period that they will be used, possibly, and it could be indefinite, whether they’re going to be informed about details of research that may be used, and whether or not they will receive research results and contact information.

So that’s all we have for this. Here are some references that you can use including the HHS final rule and some draft guidance that OHRP has put out on the Revised Common Rule.

I want to remind you, again, of upcoming ORD or Cyberseminars. The next one is October 16th and that’s Transition Provisions and an Overview of the Revised Handbook 1200.05. And we have two more in November and one in December and we’re going to get ready. And as Soundia mentioned yesterday, we’re going to look into having a special Cyberseminar to just answer questions about the Revised Common Rule and we have about, you know, 15 to 30 minutes for questions now but if we don’t get to all the questions, you can bring them to that next Cyberseminar that we’re going to have. But I’ll take questions now and see what we can accomplish and I will ask Karen Jeans and Soundia Duche and also, Petrice, if you know any of the answers to these questions or if you have any input, please chime in.

**Dr. Petrice Longenecker:** Okay so Kristina I’ll go ahead and read the questions. We have 23 total as of now. And the first one is what is the current realistic expected timeline for the updates to 1200.05 and 1200.12 in the VHA Handbooks?

**Dr. Kristina Borror:** And I will let Karen Jeans answer that question.

**Dr. Karen Jeans:** Hi everybody. This is Karen and I’d also like to start out by saying, Dr. Borror, that was an incredible presentation.

**Dr. Kristina Borror:** Absolutely.

**Dr. Karen Jeans:** So very, very, very happy. This incredible presentation that you just did on something that’s extremely complex. In answer to this question, the realistic timeline for 1200.05 first is, as we have reiterated at almost every presentation ever since we get, it is late October, first week of November. That is what we’re working for and that is the timeline and we have no reason to believe at this time that it should be any different. We understand the seriousness of getting this in as quickly as possible. So that is the working timeline and what we are planning for and how everything we’re doing is revolving around those dates. For 1200.12, I don’t have a timeline for that that I can give right now. 1200.12 while it relates to 1200.05, 1200.05 is not contingent upon the concurrent release of 1200.12. So 1200.12 is in active revision but I do not have, unlike 1200.05, a definite, you know, a definitive or a realistic date or month that I can give right now. As the weeks evolve here, I can be able to do that later. But at this point in time, I’m not able to give a month on that one yet. So thank you very much for that question.

**Dr. Petrice Longenecker:** Okay. Next question. The final rule allows subjects to continue in exempt research if they become prisoners during a study. However, am I correct that for non-exempt studies, if a subject becomes a prisoner during a study, CRADO approval would be required for the subject to continue?

**Dr. Kristina Borror:** And I guess I should have said at the very beginning of this. This is what the regulation says. But remember that VA is always allowed to have additional requirements. So it’s possible that even if the Common Rule says that you could continue in exempt research once a subject becomes a prisoner, the VA may have additional requirements for that and I will let Karen.

**Dr. Karen Jeans:** Yes. I will definitely respond on this one. VA does, indeed, have an additional layer of requirements in place that are not part of the Common Rule for prisoners that are participating in VA research. So you are indeed correct. If the investigator is made aware of individual who becomes a prisoner during VA research or, indeed, you want to recruit a cohort of prisoners, or a cohort that includes prisoners, then CRADO approval is required.

**Dr. Kristina Borror:** Thank you.

**Dr. Petrice Longenecker:** Okay. Next question. For limited IRB review, can it just be the IRB chair or will additional members need to be involved?

**Dr. Kristina Borror:** That answer is easy. As I mentioned, the regulations do allow limited IRB review to be done in an expedited manner. And so the way that the expedited review occurs is the same as expedited review for any other kind of human subjects research. And therefore, the review, if it’s determined that the limited IRB review can be done in an expedited manner and there’s no reason why it shouldn’t be, that review can be done by the chair or it can be done by an experienced member of the IRB that’s designated by the chair.

**Dr. Petrice Longenecker:** Okay. For category three exemption where it says, prospectively agree, that sounds like one does not need formal consent, written or oral consent form, is that correct?

**Dr. Kristina Borror:** That is absolutely correct. For exemption three, there is no requirement for formal informed consent. This prospective agreement is just that. It’s basically saying, the subject saying that, yes, they agree to this benign behavioral intervention and the data collection procedures. And so the regulations don’t prescribe how that occurs and so researchers, you know, are given a fair amount of flexibility for that.

**Dr. Petrice Longenecker:** Okay. With the changes to exemptions, limited IRB review, does this mean that exempt studies are coming back to the IRB and will not be initially under the R&DC committee purview? Now R&D committee handles exempt studies.

**Dr. Kristina Borror:** Well again, I’ll probably have to turn to Karen for that. But I believe that they’ll still be under the R&DC but the limit, the only exempt studies that need to go to the IRB are the ones that require limited IRB review and that is a onetime review unless the research changes so much that it’s no longer exempt.

**Dr. Karen Jeans:** Hi yeah, this is Karen. Kristina is absolutely correct. Exempt studies per 1200.01, the R&D committee are under the approval and authority of the R&D committee. So while for the applicable exempt categories, for those that do require a limited IRB review, the IRB will be reviewing for those specific criteria. They are not under the continuing oversight of an IRB. It is like Kristina said, it’s a onetime shot to determine whether or not it does fit that criteria. And then, again, it comes after the approval of the R&D committee and under its oversight.

**Dr. Kristina Borror:** Thank you.

**Dr. Petrice Longenecker:** Okay. Next question. Would Veteran health information collected by VA be considered data collected by the federal government for exemption four?

**Dr. Kristina Borror:** I don’t know if we can answer that question yet. I think that that’s a policy and maybe even a legal decision but I think there’s a good chance that it might be. I don’t know if you want to add anything, Karen.

**Dr. Karen Jeans:** Yeah this is a, there’s a number of different issues involved in that. Again data that’s VHA data in terms of what’s collected by Veterans health information is, again, health information. So in terms of exempt category four, it is referencing that category so that’s about the statements we can make right now on that.

**Dr. Petrice Longenecker:** Okay next question. How does HIPAA come into play for category four on the retrospective or perspective collection of identifiable information for research is confusing. Is a HIPAA waiver required for a VA researcher to do research on information covered in this category?

**Dr. Kristina Borror:** Yeah. So the reason why that category four related to HIPAA was added was because the idea was if the information used, the research use is already covered under HIPAA, either as a healthcare operations or research or public health activities, then it’s already covered by HIPAA and all the requirements of HIPAA have to be met, right? So you would have to either get authorization or waive it if it’s appropriate. And therefore, there was no need to have another layer of regulatory requirements, that is, there was no need to have the Common Rule on top of those requirements and that’s why that was added as an exemption. I don’t know if any from ORD have anything to add to that.

**Dr. Karen Jeans:** Yeah. This is Karen. I definitely want to add to that. And I think you’ve exactly captured the spirit and the intent of this regulation and this policy requirement for exemption. And yes, under HIPAA, there has to be authority in order to use, disclose protected health information for research purposes which differs from that for treatment, payment, or healthcare operation. So while this is under HIPAA, the authorities differ for research versus treatment, payment, healthcare operation. So a clinician cannot use the same protected health information for a treatment payment or healthcare operations and then turn around and use it for research unless there is authority under HIPAA for that use. And under HIPAA, that authority comes from an written authorization or from a waiver of authorization for research purposes. So the answer is yes, you’re either going to need to have a waiver of HIPAA authorization for research purposes or one would have to have a written authorization for use or disclosure of that information for research purposes in order to use the PHI under exemption four.

**Dr. Petrice Longenecker:** Okay. Next question. Regarding exemption four, someone in SACHRP pointed out that secondary use of identifiable information, or biospecimens, for which consent is not required if use is regulated under HIPAA is not completely accurate because identifiable biospecimens are not HIPAA regulated so it would only apply to information.

**Dr. Kristina Borror:** Okay. Yeah. I’m not a HIPAA expert. So I don’t know if Karen has anything she wants to add about that.

**Dr. Karen Jeans:** So in terms of the exemption four category, when it comes to the HIPAA issue under exemption part three, it is talking about identifiable health information. It’s not talking about the identifiable biospecimens. The first part of the exemption category when it was talking about whether or not they’re publicly available or whether or not information about the biospecimens is recorded in a way then you’re getting data about that, that’s where it gets into the data issue. But no, the HIPAA issue is not pertaining to the biospecimens. It is pertaining to the identifiable information that’s covered under HIPAA. Excellent question, thank you.

**Dr. Petrice Longenecker:** Okay. Next question. Is this new final rule now saying that HIPAA waivers are no longer needed to do research with identifiable information? Currently all use of identifiable information e.g., going into a patient’s chart would need a HIPAA waiver.

**Dr. Kristina Borror:** Karen, you want to handle that one?

**Dr. Karen Jeans:** I’ll take that one. So this is Karen again. I’m really glad these questions are asked because there are two sets of regulations in play here. The Common Rule, the federal policy which is for the protection of human subjects which is a statutory regulation, and the privacy rule which is a law, which is an act. And so the Common Rule, this federal policy that we’re talking about today does not in any way, shape, or form.

**Dr. Kristina Borror:** I’m still on a webinar. Sorry.

**Dr. Karen Jeans:** Does not say that one cannot follow HIPAA. So all this, this category four is one where there were a lot of comments about it during the ANPRM period, advanced rulemaking period, and also proposed rulemaking period. And this was one of the issues that was raised as part of the possible areas of confusion because it seems to be saying that, but it’s not. You still have to have the authority under HIPAA. If you use protected health information and you’re part of a covered entity, which VA is for example, for that use for research, so no. It does not say HIPAA no longer applies because it will apply. I’m really glad whoever asked that question and giving us a chance to talk about it on this call.

**Dr. Petrice Longenecker:** Okay. Great. Next question. Under new category four, the third and fourth criteria seem like they could apply to a substitutable proportion of VA research involving only records review, specimen analysis and/or use of data and/or specimens from a repository. It was mentioned that both criteria are a bit limited. Could you please expand a bit further what limitations apply to both of those criteria and clarify if they are logistically as broad as they appear?

**Dr. Kristina Borror:** Well we already talked about some of the limitations of exemption three, or exemption four(3) and exemption four(4) is for basically only for information. Again, this also does not apply to biospecimens. And it has to be research that was collected, generated, or obtained for non-research activities by the government. And the research or identifiable private information has to be, or will be, maintained on information technology that’s subject to, and in compliance with, a whole host of regulatory requirements. And so there’s basically a lot of requirements related to the IT and the privacy and confidentiality protections that can be used for that.

**Dr. Petrice Longenecker:** Okay. Next question. Can you talk about the difference between IRB exempt research that should have R&D review versus projects that are determined to be non-research and, therefore, not under IRB or R&D review?

**Dr. Kristina Borror:** Well remember, you don’t get to exemptions unless you have human subjects research. So the first question you ask is, is the activity research? If it’s research then there are, you know, a whole host of requirements both VA and otherwise. Then the next question you ask is does it involve human subjects? And if it involves human subjects, then the next question you ask is, it is exempt? And if it is exempt, then you see if it meets one of the exemptions that requires limited IRB review. And if it’s not exempt, then it needs full IRB review. But the other activity which you mentioned, I believe, would not involve human subjects but it could be research and would require whatever other requirements that VA has for that activity. I don’t know if Karen wants to add to that.

**Dr. Karen Jeans:** I think you couldn’t say it any better than I. I have nothing to add. I think that’s a beautiful response and absolutely agree. I absolutely agree with everything you just said.

**Dr. Kristina Borror:** Okay. Wonderful. Well I think we’re about out of time. It’s 3:30 and I want to thank you for attending our webinar. I want to thank Petrice, Karen, Cindy, and Deedee with the help on this. And when you leave today’s webinar, you will receive a survey on the presentation and we hope that you will complete that and provide your feedback. You’ll also get a follow up email within 24 to 48 hours with a link to view a recording of today’s webinar. And I want to thank you for joining us today on behalf of ORO and ORD. And as I said, if we didn’t get to all the questions, we hope to have just a question and answer session sometime in the near future. So thanks again for joining us and hope you have a great rest of your day.

[END OF AUDIO]