NIH Grants Conference PreCon Event, Human Subjects Research: Policies, Clinical Trials, & Inclusion

Day 1, December 6, 2022

An Overview of NIH Policies on Human Subjects Research

Pamela Kearney: I'm Dr. Pam Kearney, Director of the Division of Human Subjects Research in the NIH Office of Extramural Research. I'm pleased to be your moderator this afternoon. I'd now like to introduce you to Ms. Lyndi Lahl. Lyndi is a nurse practitioner by training, and she has extensive experience in human subjects research requirements both professionally and independently through serving as an IRB member. She is currently the NIH Human Subjects Officer in the Office of Extramural Research at NIH. Lyndi, you have the floor.

Lyndi Lahl: Thanks, Pam. So today, as Pam said, I will be doing an overview of NIH policies on human subjects. So during this session, I'm going to be covering three topics; one, identifying NIH policies pertaining to research involving human subjects. The second is reviewing considerations when applying for an NIH award for research that involves human subjects, and the third, identifying NIH resources for investigators conducting research involving human subjects. So the first thing we'll do is talk about those policies that involve human subjects.

So NIH has a lot of policies pertaining to human subjects research, but during this presentation, I will be introducing the policies related to human subjects in clinical research. Now please note that the NIH policies on clinical trials and the policies on inclusion will be covered in separate sessions during the December 7th pre-con seminar, so I recommend that you attend the Overview of NIH Policies on Clinical Trials and the Including Diverse Populations in NIH Clinical Research to learn more about these policy topics.

So the first question that you want to ask is, you need to know when the NIH human subjects policies will apply. Depending on what you're doing will define exactly what you have to do. So during Marianna's session, she provided you information on, how do you know if a research study is human subjects research, and what does that really mean? So she went through those three questions. Does it involve research? Is it human subjects, and is it exempt from the regulations? Now the information will be helpful when determining if the human subjects are involved in this research activity, and then tomorrow, in Dr. Kearney's session on clinical trials, she will go through the questions for determining if a human subjects research study is a clinical trial. I do want to note that the NIH human subjects policies are complementary or in addition to the Common Rule requirements.

So the first policy I'm going to talk about is the NIH policy for education on the protection of human research participants. It's been a requirement for over 20 years. All key personnel, which include all individuals responsible for the design and conduct of the study, must have completed training in the protection of human subjects. Now, this educational requirement

also pertains to key personnel at alternate performance sites, including non-U.S. sites as well as key personnel that begin after the award is funded. Now, NIH expects the key personnel receive the required training before they are involved in the research. Now please note that NIH does not mandate any specific course that the key personnel need to take or the specific content that's included in the course. This is a one-time training requirement, and as Marianna shared with you during her presentation, OHRP has a free training on human research protections that will satisfy the NIH educational requirement for key personnel.

Now, all NIH-funded research that is ongoing or awarded on or after December 13th of 2016 and is within the scope of the NIH Certificate of Confidentiality policy - I will often call this CoC or Certificate, talking about the same thing. It's deemed to be issued a Certificate. Now, as an investigator of a NIH-funded research study, it is your responsibility, along with your institution, to determine if your research is collecting or using covered information, since that's what the Certificate protects, covered information. Now, covered information includes the name or any information, physical document or biospecimen that contains identifiable sensitive information related to a research participant, and in addition, if there's at least a very small risk that the information, document or biospecimen can be combined with other available sources to determine the identity of an individual, these are also protected by a Certificate. Now I want to note that covered information that is collected or used by a subrecipient who receives funds to carry out part of your NIH award are also protected by the Certificate, and in addition, secondary researchers that receive information protected by a Certificate are also required to uphold the CoC protections. As the investigator, you will need to inform any subrecipients that the CoC protections apply and any secondary researchers that you're providing that information to when it is protected by a Certificate. Now, the protections of a CoC last in perpetuity, so that means that the data that you collect during your NIH funding will remain protected by the CoC even when your NIH funding ends. Now please note if your research continues after your NIH funding ends, and you continue to collect new data or enroll new participants, that newly collected data or those newly enrolled participants will not have the benefit of protections by a CoC. However, you can request a Certificate to provide CoC protections for that data that is covered after your NIH funding ends, and there's more information about requesting a CoC for research that is not funded by NIH, which would be the case if your NIH funding ends, and it can be found on the NIH CoC web page.

So this topic is so important, I have a second slide on it. So you and your institution are prohibited from disclosing or providing information protected by a CoC, and that would be in any federal, state or local civil, criminal, administrative, legislative or other proceeding or to any other person not connected with the research. Now, there are limited circumstances when you or your institution may release participants' identifiable sensitive information. Such disclosure is only permitted when required by other federal, state or local laws such as for public health reporting of communicable diseases or child or elder abuse reporting, or if it's made with the consent of the subject, or if it's necessary for the medical treatment of the participants, and it's made with the consent of the participant, or if it's made for purposes of scientific research that

is compliant with the human subject regulations. Now I do want to clarify something that I just mentioned. Disclosure of identifiable sensitive information protected by a CoC must be done when the disclosure is required by other federal, state or local laws. Now, there is a distinct difference in receiving a subpoena or request from law enforcement for information covered by a CoC, and you are prohibited from disclosing under those circumstances. However, let's say there is a public health reporting requirement at the state level that you report the name of a participant with a communicable disease. It's mandatory reporting, so you must report under those circumstances.

Okay, so you heard a little bit about single IRB under the revised Common Rule with our last session and Dr. Lau, but I do want to make sure you are aware that there are two similar but separate requirements for use of a single IRB for non- or for NIH-funded nonexempt human subjects research. Now, the NIH single IRB policy became effective in January of 2018, and the compliance date for the revised Common Rule Cooperative Research Provision was in January of 2020. Now, you can learn more about these two single IRB requirements on the NIH single IRB for multi-site or cooperative research web page, or better yet, stay for the final session of the day which immediately follows this session, and that is going to cover the essentials of single IRB requirements.

So delayed onset generally means that human subjects research is anticipated within the period of the award, but the application or the proposal that you've submitted does not include any definitive plans for this involvement, and please note that a delayed onset research does not apply to a study that can be described but is not going to start immediately. This is called delayed start. Kind of makes sense, right? Now, if you have any questions on whether your research, in your application, is delayed onset research, I recommend that you contact your program official listed in the Funding Opportunity Announcement for guidance. Now, if you are recipient of a single-project award, and you have a delayed onset research, this may be because you are waiting for results from initial preclinical research before the human subjects research can be fully planned. You will need to submit a prior approval request in writing to your grants management officer for the funding institute or center no later than 30 days before the proposed change. Now, this will need to be signed by your authorized organization representative in accordance with the NIH Grants Policy Statement. Now, you'll need to provide a newer revised human subjects section that clearly describes the risks, methods, protections and the importance of the knowledge to be gained by the revised or new activities, and in addition, you're going to need to provide other applicable documentation such as the certification that the key personnel have taken appropriate education for the protection of human subjects and a new or revised inclusion plan for women, minorities and children.

Now, there are two other awards that are associated with delayed onset research. This includes cooperative research or multi-project awards and award mechanisms that allow a portion of the budget to support small human subjects research projects that is awarded to a different institution, and those are often known as pilot projects. Now, you'll need to follow the

instructions from your funding institute or center for prior approval of your projects, and note you'll also need to submit appropriate inclusion enrollment information as well, as well as any other requirements that the institute or center has.

Now, although human fetal tissue isn't exactly human subjects research, I thought it was good to include this information as well. Research involving human fetal tissue is defined as research involving the study, analysis or use of primary human fetal tissue, cells and derivatives and human fetal primary cell cultures that are obtained from elective abortions. Now, if you are submitting an application for research involving human fetal tissue, you need to justify the need for the use of the human fetal tissue for the proposed research, and you'll need to include sufficient details in your description that allow a meaningful evaluation by NIH. You'll also need to include all required information, such as a detailed budget. Now please note if you're proposing research involving the use of human fetal tissue, you cannot use the PHS 398 Modular Budget Form. Instead, you'll need to use the R&R Budget Form, and I do want to note also that these additional requirements must be met within the existing applicable page limit, and if your application does not address all the information that is required, it is going to be withdrawn, and it will not be reviewed.

Okay, I have a couple of polling questions within this slide set, and this is the first of three. And the polling question, is it true or false? Investigators and all key personnel involved in human subjects research that is determined to be exempt from the regulatory requirements in 45 CFR 46 must meet the protection of human subjects educational requirements. So DeRon had launched the poll. Thank you, DeRon. And I want you to go ahead and answer true or false. Do you think that the investigators and all key personnel need to have the human research education if they are conducting exempt research? Okay, the poll is closed, and 82 percent of you said true, and that is accurate. So let me ... Whoops. Uh-oh. I went too far. Okay, there. So the correct response is true. Similar to the educational requirement for nonexempt human subjects research, investigators and all key personnel involved in human subjects research that is determined to be exempt from the regulatory requirements of 45 CFR 46 must still meet the protection of human subjects educational requirement, and this also includes key personnel at performance sites as well.

Okay, so the next polling question, it's also a true or false. NIH will provide a physical certificate for my NIH-funded research project to document CoC protections. So thank you, DeRon. You just launched the poll. This is a true or false question, so please go ahead and answer if you think that NIH provides a physical certificate when you have an NIH-funded research project that has covered information and offers CoC protections. Okay, the poll is closed, and 28 percent people said true, and 72 percent said false, and the majority of you were correct. The correct response is false. NIH does not issue a physical certificate for NIH-funded research projects. Now, it's the NIH CoC Policy, the Notice of Award and the NIH Grants Policy Statement, if you have a grant award, and the NIH DGS Contract Handbook-Special Contract Requirements, if you have an R&D Contract, and those documents will provide the

documentation of the CoC protections. Now please note that institutions and their investigators are responsible for making the appropriate determination as to whether the research that you're conducting involves the collection or use of identifiable sensitive information and is subject to the CoC policy and is therefore deemed to be issued a Certificate. So NIH will not tell you if the policy applies and if you have CoC protections. It is up to you to make that determination.

Okay, and the third and final polling question, so under the CoC Policy, an investigator may release a participant's identifiable sensitive information, and we have five different answers. Is it A, if required by institutional policy; B, if the participant consents; C, if the investigator decides it is appropriate to disclose identifiable sensitive information; D, all of the above; or E, none of the above? So go ahead and respond, tell me what you think. When can you release a participant's identifiable sensitive information? Okay, it looks like the poll has closed, and it looks like almost half of you said it's when the participant consents, and over 1/3 of you said none of the above, and then there's a mix, a few that said everything. So the correct response here is B. Under the CoC policy, an investigator may release a participant's identifiable sensitive information when the participant consents to such disclosure. An institutional policy does not give the investigator the authority to release the participant's identifiable sensitive information, and an Investigators cannot decide on her or his own that the participant's identifiable sensitive information can be released. Now please note that when other applicable federal, state or local laws require disclosure, as we talked before about communicable diseases and public health disclosure of that, disclosure of identifiable sensitive information protected by a CoC must be disclosed. I recommend that you see the NIH CoC website, Investigators and Institutional CoC Responsibilities, and there is a hyperlink here, for the limited circumstances under which an investigator or institution may release participant's identifiable sensitive information and other responsibilities as well. Now, you can also go back and view slide eight in this slide set, and that's posted now for the day one, and that will include the limited circumstances when disclosure is permitted.

Okay, we're going to go on and think about review considerations when applying to NIH for an award that will support research involving human subjects. So as you know, or as you may know, the HHS regulatory requirements of 45 CFR 46.120 says the department or agency will evaluate all applications and proposal involving human subjects that are submitted to the federal department or agency, and the department or agency can utilize experts and consultants as determined to be appropriate, and for applications and proposals submitted to NIH, the agency that will conduct the evaluation is NIH. Now, this evaluation will take into consideration four specific things, the risk to the subjects, the adequacy of the protection against these risks, the potential benefits of the research to the subject and others and the importance of the knowledge to be gained, and on the basis of this evaluation, NIH may approve or disapprove the application or proposal or enter into negotiations to develop an approvable one.

So in the next two slides, I'm going to be focused on the plan protection of human subjects that you'll need to address in your NIH application. Risks, you need to consider if your application adequately describes human subjects involvement, the characteristics and design, the source of material and potential risks, so think about the following things. Do you have a description and justification for the proposed involvement of human subjects, including your planned enrollment numbers, the age range of the participants you plan to enroll and the health status of those participants? Do you have a rationale for the involvement of vulnerable populations, such as pregnant women, children, prisoners or institutional individuals? Is the role of any collaborating sites described? And this would be where research is going to be performed outside of your institution. Do you describe and justify the research procedures that you plan to do? Do you describe research materials, data and information you plan to collect? Will you have access to personally identifiable information that is collected and retained? Have you identified all potential risks to the participants, including the likelihood and the seriousness of those risks when it comes to physical, psychological, financial, legal and other risks? And do you address how you will handle incidental findings that may occur during the research? Now, the second piece, adequacy of the protection against those risks. You need to think in your application, are you adequately describing the recruitment and the informed consent and the protection against the risks? This would include, how are you recruiting your participants? Do you describe the informed consent, parental permission or assent that you're going to be obtaining, or do you plan to request a waiver of consent from your IRB? How will you minimize the risks that you've identified? What additional protections do you have for any vulnerable populations that will be part of your research? And do you have the necessary medical or professional folks available if there is an adverse event that you need to address when a participant has an AE? So potential benefits of the proposed research to the participants and others, so does your application adequately describe how potential risks to the participants appear reasonable in relation to any anticipated benefits? And I do want to note that financial compensation of participants should not be presented as a benefit of participating in the research. In the fourth and final plan for the protection of human subjects that you want to make sure you address is the importance of the knowledge to be gained. So does your application adequately describe how potential risks to the subjects appear reasonable in relation to the importance of the knowledge that may result from the study?

Now, many of the concerns that have been identified by peer reviewers are due to the lack of information or inadequate description of one or more parts of the plan for the protection of human subjects. So that's why you need to include the details that will provide the reviewers sufficient information, so they understand that the protections that will be available to your participants. Now, there are some common concerns involving human subjects that are often identified during peer review. Now, the most common concern by peer reviewers is that the application had general deficiencies in the protection of human subjects section. Now, that's not very helpful because general deficiencies probably mean there's more than one piece that wasn't sufficient. Surprisingly enough, there's missing or inadequate data in safety monitoring

plans that is often a problem when it comes to clinical trials and peer review. They don't have good Data and Safety Monitoring Plans. There may not be any information addressing incidental findings which is vital in these plans. The risks may not be adequately addressed, and that would include all those risks I talked about in the previous slide. There may be inadequate protections for vulnerable populations. The source of the specimen or data is not addressed, or the application did not clearly delineate whether investigators have access to participant identifiers, and you can think about the first two presentations that we had today with Marianna and Yvonne, and it's really important for the reviewers to understand whether or not human subjects are involved. If you do not get any identifiers with your specimens, human subjects may not be involved, and if that's the case, then the protections aren't relevant because there are no human subjects involved in the research, and then the planned recruitment activity sometimes appears to be coercive.

So when NIH needs additional information from a grant applicant, the Just-in-Time period provides a tool to facilitate this purpose. So Just-in-Time, sometimes called JIT, allows you and the signing official to submit certain elements of a competing grant application at a later date in the application process. This is done after peer review and when the application is being considered for funding. Now, there are several pieces of information that are collected at Just-in-Time. This includes the Federalwide Assurance Number if the institution has proposed nonexempt human subjects research, and you heard all about FWAs in the last session, the certification of IRB approval, and that's satisfied by submitting the latest IRB approval date. Now, for most this is going to be your initial IRB approval date, but we do sometimes fund studies that are ongoing, and it may have been more than a year since the initial IRB approval, and if that is true, you would need to submit the latest IRB approval date, and then of course the institution needs to provide certification that all key personnel involved in the human subject research has completed the educational requirement in the protection of human subjects. Now, this is also the time in which you will submit a request for an exception to certain policies. Now, if the project is exempt under Category 5, your program official is actually the one that will be prompted to submit this policy exception request for Exemption 5, and I'm going to talk a little bit more about this in the next slide. Now, if you want to request an exception to the single IRB requirement, this will be the time that you will submit this request, and stay for the next session, as I mentioned before, to learn more about the relevant information that needs to be submitted if you decide to seek an exception to the single IRB requirements. And this is also when a policy request, and this again is going to be done by your program officer, for Public Health Surveillance Exclusion would be submitted, and if you remember back to Marianna's presentation, this is one of those exclusions that if you're doing public health surveillance, you're not doing research because it is excluded. NIH developed a process for this earlier this year, and I recommend that you look at the NIH website, Public Health Surveillance Exclusions, for additional information. Now please note that it is rare for NIH to receive or approve any of these policy requests.

So let's go back and talk about Exemption 5 for just a moment. So Exemption 5 is research and demonstration projects that are conducted or supported by a federal department or agency and are designed to study, evaluate, improve or otherwise examine public benefit or service programs. Exemption 5 research activities must be posted on a federal website prior to the research being initiated, and NIH will post NIH-supported Exemption 5 research activities when the activity is designated as such. However, a determination of Exemption 5 research is typically made in error. It seems that folks get a little bit confused, and it's expedited Category 5, not Exemption 5 research. At least that's what we've found, so NIH is going to review a determination of Exemption 5 to confirm it's appropriate, and today, since the revised Common Rule went into effect, NIH has supported zero Exemption 5 research activities. So we have not seen any true Exemption 5 research, and we do not anticipate that we are going to receive any because it's not something that NIH will do in general.

So if you will be involved in a multi-site study, you need to be aware of information that is on this slide. So in general, the prime recipient of a NIH award is considered engaged in human subjects research even when all activities involving human subjects are carried out by employees or agents of another institution, and, of course, Yvonne talked about this a bit in the previous presentation. I recommend that you review the OHRP guidance document, Engagement of Institutions in Human Subjects Research, if you'd like to learn more about engagement, and the link to this guidance document can be found in the resource document that's listed on the resource slide at the end of this presentation. Now the reason that this is relevant is because all sites that are engaged in nonexempt human subjects research need to be covered by a Federalwide Assurance, and again going back to Yvonne's presentation, she included the information about FWAs. In addition, each of these sites will also need to have their activities reviewed and approved by an IRB, and when there's more than one US site that is engaged in the research, the single IRB requirements will apply.

Now, a subaward allows a different institution to perform some of the activities under the NIH award, and if you're the prime recipient of an NIH award, it is you and your institution's responsibility to supervise these activities that are being done by your subawardee. Now, there's going to need to be a formal written agreement that addresses the specifics of this arrangement, and this will include identifying who is the lead investigator and other individuals who are responsible for the research activity along with their roles as well as any financial aspects of this arrangement. Now, the subaward or a pilot project investigator must obtain IRB approval before involving human subjects in the nonexempt human subject research activities, and please note the single IRB requirements may apply. Again, the next session will delve into that. Now, it's going to be the recipient institution that submits progress reports to NIH that includes relevant information on all the subawardee activities, including these pilot projects, and lastly, I do want to note that all applicable NIH policies and applicable regulations will apply to subaward and pilot projects. This includes the NIH regulations at 45 CFR 46, the educational requirements for human subject protections and the NIH Certificate of Confidentiality Policy amongst many others.

Okay, well, we are getting close to the end, so objective three was to identify NIH resources for investigators conducting research involving human subjects. So a few years ago, after the revised Common Rule came into effect, NIH developed a quick decision tool that can assist you in determining if your research involves human subjects, if it may be exempt from the federal regulations or if the activity is not considered human subjects research. Now please note that this tool should not be used as the sole determination of whether your study is exempt from the regulations, and the tool is available on the NIH Grants and Funding website, and there is a hyperlink here to be able to get to the tool from this slide.

So the resource page, I had mentioned that third bullet resource document. That's a compilation of a lot of different resources, both on the NIH site and on the OHRP site, and it will be very helpful to you, and this hyperlink will get you right to that. In addition, the NIH Human Subjects Research Home Page and the Office for Human Research Protections Home Page also have a lot of information that is available to you. So I would be happy to take any questions at this time. Pam, I am going to turn it over to you, so you can tell me what questions we might have.

Pamela Kearney: Great, thank you, Lyndi, so much for that interesting talk. We have a number of questions in the Q & A. I doubt we'll get to really even close to all of them, but we'll give it a shot. Why don't we start with: Someone was asking if you could clarify that, for cooperative research, whether the requirement for single IRB extends to include protocols that receive limited IRB review.

Lyndi Lahl: That's a great question, and I'm actually going to mention this in the next presentation, but I'm happy to mention it here as well. So limited IRB review is something that's done for certain exempt research activities, and I think there's four different exemptions and then underneath that exemption, it's not all Category 2 exempt research that will need limited IRB review, but certain parts of it. So the short answer is no. The single IRB requirements do not apply if there is a limited IRB review that's required. It's only when it's nonexempt human subjects research.

Pamela Kearney: Okay, thank you. So here's another question about research conducted outside of the U.S. Does the CoC also protect - And here's an interesting phrase. Does the CoC also protect investigators conducting research outside of the U.S. from disclosing identifiable information required by that country's government officials? If such an instance occurs, what should the investigator do?

Lyndi Lahl: Yeah, so that's a good question. We do get this question on occasion, and the bottom line is the policy was developed to protect all the participants in NIH-funded research. However, outside the U.S., the CoC protections may not be applicable. So if your country's laws mandate disclosure, a CoC is likely not going to provide the protections it would if the participants or data are located within the U.S. The CoC is also made to protect participants. It is not designed to protect the investigators or the research staff either, so I want to make sure that I get that part in. I've heard horrible instances of when there has been disclosure outside of

the U.S. But it was done on behalf of the government where the research was being conducted, that's not in the U.S., and there, really the CoC is not going to be able to help you with that.

Pamela Kearney: Lyndi, as a follow-up to that, can you talk about the consent requirements regarding CoC coverage? Because that sounds like it would be something that participants would need to know.

Lyndi Lahl: Yeah, absolutely. So NIH expects that the investigators are going to inform their participants when there is a CoC in place. Now, that would likely be through the informed consent. It needs to be through some mechanism. So NIH has sample language on the CoC website that you can use, or you can adapt to your use, but we do expect that you are informing participants, and most likely you'll want to work with your IRB because the IRB may have specific ways not using NIH language, maybe their own language, to be able to inform the participants of those CoC protections, and it's not just the protections that need to be addressed in the consent. You also need to address any limitations to those protections. So if, let's say you are doing research on a vulnerable population. Let's say it's children that have been abused, and you find out that there has been abuse for this child participant. There is going to be a mandatory disclosure that you're going to have to disclose that information. You would have needed to put that in the parental permission form, and if you're getting child assent, you would need to have included that because that is a limitation to those protections.

Pamela Kearney: Mm-hmm. Okay. We have a couple questions asking about examples of incidental findings.

Lyndi Lahl: Okay. So incidental findings, in case you don't know, are something that happens, that you find out, that you weren't looking for, you weren't anticipating, but you found out anyway, and it's something that is about your participant. So let's say you are doing some research, and you're doing some MRIs of the brain, and it's because you're looking for some cognition, and in the course of doing this MRI, you notice that there is some abnormality. If it's actionable, you're going to want to disclose that incidental finding to your participant. You likely will have the information of who referred that person, if the person came from a medical provider, and when I talked about the incidental findings and what you plan to do if you have them, this is exactly why you would want to include those plans in your human subject protection plans in your application because you need to know what you're going to do. You need to have a plan in place.

Pamela Kearney: Mm-kay, thanks, Lyndi. Let's see. We have a couple more here. Okay, here is a question about patient consent for disclosure, and the attendee asks basically, how relevant is the patient consent to release the information if others don't consent to it, as it relates to the CoC, and I'm not exactly sure what they mean by others. I'm thinking family members. I'm thinking maybe other researchers or that sort of thing.

Lyndi Lahl: Okay, so I want to make sure that I have the question. So if your participant consents to disclosure of their private, identifiable sensitive information, but let's say their spouse or someone else does not agree to that disclosure, what do you have to do? Is that kind of the ...

Pamela Kearney: That's what I'm assuming.

Lyndi Lahl: Okay.

Pamela Kearney: I just read it to you basically the way it came in.

Lyndi Lahl: Yeah. So .

Pamela Kearney: But I think it ...

Lyndi Lahl: So I ... Yeah.

Pamela Kearney: I think it has to do with the autonomy of the person to give their consent to release it, is the way I'm taking this.

Lyndi Lahl: Yeah, so under the CoC Policy, you are permitted to disclose that information, and I think it's kind of expected that if the participant says that you can disclose to, let's say the police because the police are asking for this, then you can disclose that. If it's for other medical purposes, let's say there's an incidental finding, the participant will need to consent, and then you're going to be able to release that information to their medical provider, who is not a researcher. It might get a little uncomfortable if, let's say the spouse doesn't want you to disclose that, but it really is, as you said, Pam, it's the autonomy of the participant.

Pamela Kearney: Okay. We had a follow-up question to one that was answered just by typing the answer in, and it had to do with the definition of identifiable sensitive information. The link was provided, and an excerpt of the definition was provided, and the follow-up question is relating to genetic information or tissue samples, and the question specifically is, does every study that includes genetic information or tissue samples, are they considered sensitive information, and therefore, would that necessarily need a CoC?

Lyndi Lahl: So the short ...

Pamela Kearney: Or would it be deemed issued to have a CoC?

Lyndi Lahl: Yeah, yeah, yeah. Yeah, so the short answer to that is yes. Likely it is going to be deemed to be issued a CoC. It's not just about having those identifiers. You don't have to have the person's name or other type of sensitive information. If there is a very small chance that you can identify someone with the information that you have .. . And when I say information, that's broad. That also includes specimens, data, et cetera, and it can be combined with anything else, then it is also deemed to be issued a Certificate. So I don't want to say 100 percent yes, but it is most likely.

Pamela Kearney: Okay, thanks, Lyndi.

Lyndi Lahl: [Indistinct] Mm-hmm.

Pamela Kearney: Thanks, Lyndi. Someone else is asking if you could address the question of patient samples that were collected while the patient was alive, and there was a CoC issued, but now the patient is deceased, but the patient was consented and was part of this CoC, and data and information was collected under that CoC, but now the patient is deceased.

Lyndi Lahl: Yeah, so going back, when I talked about Certificates, you might remember I said Certificates are, the protections are in perpetuity, so that means that they are going to protect even the data from a deceased individual. So you cannot just release the deceased individual's private sensitive information. You would need to then look at your state laws and regulations on who can give consent if you want to release that information and probably talk with your institutional lawyers about how you would go about being able to release that information if it's appropriate or if you want to do that.

Pamela Kearney: Okay. There are a couple of questions that I'm not really sure what is being asked, so I may come back to those and just ask a question the way I think it was going to be asked. There is a question here that - It was actually a two-part question, and the question reads, "IRB training is separate from HIPAA training, but both are needed, no?" So I think the question is, is IRB training needed, and is HIPAA training needed for NIH-funded studies?

Lyndi Lahl: Well, so NIH is not a covered entity. NIH is not OCR, Office of Civil Rights, so NIH is not going to require that you have HIPAA training. Now that being said, most IRBs serve as the privacy group that and is HIPAA language in addition to looking at the research and looking at informed consents. Again, NIH policies don't really speak to IRB training, and this would have been a great discussion with Yvonne because she is from OHRP. I can tell you as an IRB member for over 10 years, and, Pam, you were an IRB chair for many years, I hesitate to say IRB training for your IRB members is not required because I shudder to think that there are IRB members out there that are not being trained, but it certainly is not an NIH requirement. And you can add if you have anything else to say about it.

Pamela Kearney: And we're getting short on time, so we only have time for a couple more. Another question is, how long should a principal investigator hold on to the identifiable information? And I'm always going to put on the end of that "for NIH-funded studies" because that's what we're talking about so ...

Lyndi Lahl: Yeah, so it really is going to be between you and your IRB how long the identifiable sensitive information is retained. You're going to do the research. You are going to maintain that information in a place where you're going to be able to secure it, and you're probably going to want to go back and do some QA to make sure, when you're doing your data analysis, everything is good, but in terms of NIH requirements, there's not a specific requirement that says you must retain it for a certain length of time. Certainly look to the FDA, if you're doing FDA-regulated research. They have requirements under I&D, how long you need to maintain it. If there was ever a question, you would want to be able to have the information to be able to defend what you had done, so I wouldn't be getting rid of it right away, but again, talk to your

IRB about what information you're going to retain with identifiers and how that information is going to be maintained.

Pamela Kearney: Okay, and we probably have time for maybe one or two more. We had a couple of people up-vote a question about the one 18 letters in the Common Rule and whether or not it can be used if IRB approval hasn't yet been secured at Just-in-Time. We might need one of our colleagues from Grants to answer this one, but I thought I would throw it out and see if you have the answer to that, Lyndi.

Lyndi Lahl: Yeah, so I think they're talking about the delayed onset research.

Pamela Kearney: Mm-hmm, yeah, Dawn is shaking her head yes. So Dawn is up there, yeah.

Lyndi Lahl: Yeah, so and, Dawn, let me talk a little bit, and then if you want to add on, you're more than welcome. So it may be that the grant can be awarded with restrictions that no human subjects can be involved until such time that you have submitted that information that's needed, that the IC has been able to review and make sure that everything is acceptable, and then they would take the restriction off the award. So, Dawn?

Dawn Corbett: Yeah, Lyndi, I think you covered it. I think that's right. You would just need to submit that information when it becomes available and you can describe the protocol, and then that restriction can be lifted.

Lyndi Lahl: Great, thanks.

Pamela Kearney: I think we literally have about 30 seconds, so I am reluctant to go into another question. So I'll stop here and thank Lyndi very much for a great talk, and I want to thank all of you for joining us today for this talk. The PowerPoint and the related resources are located in two different locations. You can find it on the NIH Grants Conference website and also inside the Virtual NIH Grants Conference Center. Look for the Human Subjects Research Pre-Con Event Page.