4-3-13 Webinar "When the Assurance Comes a 'Knocking': Everything You Need to Know About OHRPs, FWA, and IRB Registration Processes"

>> SUMMERS: Good afternoon, everybody. I apologize once again for the technical difficulties, but I hope you all can hear us now. This is Elyse Summers. I am the director of the Division of Education and Development at the Office for Human Research Protections. Welcome to our fourth educational webinar, "When the Assurance Comes a 'Knocking': Everything You Need to Know About OHRP's, FWA and IRB Registration Processes."

These webinars, begun just over a year ago, are an important component of the Division of Education'a menu of opportunities, which also include in-person learning activities, such as our major Research Community forums and our hands-on Quality Assessment Workshops.

Keep an eye on our website and your e-mail in-box throughout the year for real-time information about the full panopy of OHRP educational programs.

Today, three of my wonderful colleagues from OHRP's Division of Policy and Assurances, Division Director Dr. Irene Stith-Coleman; Assurance Team Leader, Dr. Harold Blatt, and Assurance and IRB Coordinator, Ms. Jeannie Makle, will be discussing the requirements and processes involved in registering institutional review boards and obtaining Federalwide Assurances under the HHS regulations at 45 CFR part 46. This webinar is a basic offering, well suited to those of you who are new to the field of human subjects research and protection and to those of you who are not so new but wish to refresh and reinforce your understanding of the HHS

regulatory requirements. At this point I would like to take a few moments to cover some of the logistical aspects of our program and as many of you have already seen, the logistical aspects are not always as easy as they might appear. If you happen to have difficulty hearing the presentation, you may want to switch your audio selection from telephone to voice-over-Internet provider or VOIP or vice versa.

Next, I want to mention that in as far as there will be 1,000 or more of you in cyberland listening to today's presentation, it will not be possible to take questions at any point during this session. As always, you may, of course, send along any questions you have related to this presentation to the general OHRP mailbox, OHRP@HHS.gov and we will answer them promptly in our normal course of activities. Also, if you would like to review this webinar and/or share it with colleagues, the recorded presentation will be posted to OHRP's YouTube channel within the next several weeks. You will find the link on the other OHRP website at that time. Many of you undoubtedly know that our first three webinars on respectively: "Compliance Activities," "Nuts and Bolts," and "Investigator Responsibilities" are already available on YouTube.

Finally, I want to thank Lannette Myers and Samantha Smith who, along with our wonderful DPA colleagues, are the brains behind this operation and have worked diligently to ensure the smooth production you are about to enjoy today. Now it is my pleasure to turn the mike over to Dr. Irene Stith-Coleman. Irene.

>> STITH-COLEMAN: Good afternoon. I, along with my two colleagues, Jean Makle, and Harold Blatt are delighted to talk to you about OHRP’s, FWA and

IRB registration processes this afternoon. As an overview, I will give you a brief overview of the regulatory basis for obtaining a Federalwide Assurance, or FWA, and registering Institutional Review Boards, or IRBs.

First, when -- or why and when are assurances of compliances required?

The U.S. Department of Health and Human Services protection of human subjects regulations that are found at 45 CFR part 46 require institutions, both U.S. institutions and nonU.S. institutions to hold or obtain an assurance of compliance before engaging in HHS conducted or supported research that is not exempt under these HHS regulations.

In addition, these HHS regulations require institutions to certify to the HHS agency conducting or supporting the research that the research has been reviewed and approved by an IRB, and that the research will be subject to continuing review by an IRB. Of note, IRBs must be registered with OHRP before they review HHS-conducted or -supported nonexempt human subjects research.

When is an institution engaged in nonexempt human subjects research? In general, an institution is engaged in nonexempt human research when its employees or agents obtain data about living individuals for research purposes through intervention or interaction with those individuals; or obtain individually identifiable private information for research purposes; or obtain informed consent of subjects. Therefore, if the institution's employees or agents do either one of these three things, then that activity would trigger the requirement for the institution to be covered by the assurance and IRB certification requirements I just mentioned.

Regarding the assurance requirement, the FWA is the only type of assurance

that OHRP accepts or approves. Through its FWA, an institution pledges to conduct its HHS funded and or conducted research in compliance with HHS's protection of human research regulations. In addition, if the FWA institution is a U.S. institution, it may also voluntarily pledge to conduct all of its nonexempt human subjects research, regardless of the funding source, in compliance with 45 CFR, Part 46. This option is often referred to as "check the box."

Of note, two-thirds of U.S. institutions currently "check the box." That is, they optionally elect to apply either the Common Rule to all of their research, regardless of source of support; or they optionally elect to apply the Common Rule and subparts B, C, D, and E of 45 CFR part 46 to all of its research, regardless of source of support.

The Common Rule is the federal policy for the protection of human subjects; it has been adopted by 15 federal departments and agencies, including the Department of Health and Human Services.

In addition, several other federal departments and agencies also comply with the Common Rule. HHS's adoption of the Common Rule is captured in subpart A of 45 CFR part 46.

Other Common Rule departments and agencies accept the FWA for human subjects research that they support. However, some Common Rule department or agencies also issue their own assurance for the research that they conduct or support.

Now that you have heard about the regulatory basis for an assurance of compliance, I would like to briefly mention why and what IRBs must register. The protection of human subject regulations in subpart E of 45 CFR part 46

require IRBs that review HHS-conducted or-supported human subjects research to register with OHRP. In addition, OHRP's sister agency, the Food and Drug Administration, also has IRB registration regulations, and they are found at 21 CFR part 56.106. Those regulations require each U.S. IRB that reviews clinical investigations regulated by FDA or that reviews clinical investigations intended to support applications for research or marketing permits for FDA-regulated products, to register.

Both OHRP-covered IRBs and FDA-covered IRBs register at the same website that is maintained by OHRP.

Lastly, it's important to note that registering IRBs and obtaining OHRP-approved FWAs are two separate processes. This is a confusing concept to a number of institutions and organizations, so I would like to just emphasize that they are two separate processes. In closing, I would like to provide information on the approximate number of IRBs currently registered with OHRP and also the number of OHRP-approved FWAs. As of March 5, there were more than 5800 IRBs, 61% domestic and 39% are international IRB; and, more than 12,000 FWAs, more than 9,000 domestic institutions FWAs and close to 3,000 international. Of the 9,000 domestic FWAs, more than 6,000 have optionally "checked the box," that is, 66% of domestic FWA institutions have optionally checked the box.

With that, I will turn it over to my colleague, Jean Makle, who will now walk you through the IRB registration process.

>> MAKLE: Good Afternoon, I am Jean Makle. Today I will walk you through the IRB Process; however, before we start, I would like to pause for you to participate in a poll to find out if you have ever submitted your

organization's IRB registration.

Please select yes or no. I would like for all of you to participate.

All right. The poll has closed.

I noticed that 62% of you said yes. So that may mean that many of you probably have a good understanding of the IRB registration process.

The first thing I am going to talk about this afternoon is about the required process for submitting registrations to OHRP. Registration applications must be submitted electronically using OHRP's Electronic Submission System , known as the ESS, unless an institution lacks the ability to submit electronically. You will see the URL for the ESS on the screen.

The next four slides include information that must be provided when registering your organization’s IRB. You must provide the name and mailing address of the organization operating the IRB, the IRB organization’s Head Official and Contact Person contact information - name, address, phone and fax numbers and email address. In addition, each IRB’s address, phone and fax numbers and email adress, and the IRB chairperson’s name, phone number and email address. For each IRB, the approximate number of full-time equivalent devoted to the IRB'S administrative activities must be provided; the approximate number of all active protocols being reviewed by the IRB; and, the approximate number of active protocols conducted or supported by HHS, for example, NIH, CDC, et cetera, being reviewed by the IRB. For the purpose of registering, an active protocol means any protocol for which the IRB conducted an initial or continuing review in a convened meeting or under

expedited review during the preceding 12 months.

Each IRB in the U.S. that reviews protocols regulated by the FDA must provide the approximate number of active protocols involving FDA-regulated products, and a description of the types of FDA-regulated products in protocols, such as human drugs, medical devices, biological products, food additives, color additives, and other; if other is selected, specify.

Now, let's talk about the IRB Membership Roster, required for OHRP-covered IRBs but not FDA-covered IRBs. An IRB Membership Roster must include at least five members, including the IRB chairperson. For each IRB Member, the following information must be provided: name, gender, earned degree(s), whether a scientists or nonscientist, and whether the IRB Member is affiliated with the IRB organization.

The last three slides I will talk about will include several frequently asked questions that we receive and the answers.

The first question is: How will an organization know its submitted IRB registration has been reviewed and accepted by OHRP?

Once OHRP reviews and accepts the registration, the organization's contact person, head official, and the IRB chairperson all will receive an automatically-generated email, informing them that their organization's registration has been accepted. In addition, a copy of the reviewed and accepted registration will be attached to the email.

The second question: When must an IRB registration be updated or renewed? IRB registrations must be updated within 90 days after the Contact Person or the IRB Chairperson changes. An organization must renew its registration every three years, even if no changes have occurred, in order

to maintain an active registration.

Any IRB update or renewal electronically submitted to and accepted by OHRP renews a three-year effective period.

My last slide addresses disbanding of IRBs. An organization decision to disband a registered IRB must be reported to OHRP in writing within 30 days after permanent cessation of the IRB's review of HHS conducted or supported research.

Now that you have heard about the IRB registration process, you will now hear from my colleague, Dr. Hal Blatt, about the FWA process.

Thank you.

>> BLATT: Good afternoon. I will be discussing the FWA process, but before I get started, I would like to take a poll to get an idea about how many of you are responsible for submitting your institution's FWA. We will pause so you can respond to the poll. Please select yes or no.

Okay. It looks like it's closed and the majority say yes, that they are responsible. Well, that's great. That means that a lot of you already have a good idea and a good understanding of what I am about to say.

Now, the first item I would like to discuss is the ESS requirement. Institutions must submit their FWA applications electronically using OHRP's electronic submission system or ESS, and on the slide you see the URL address. This must be done unless an institution lacks the ability to submit its FWA application electronically. But this is a very rare occurrence. Most organizations can do the submissions electronically.

And then the second thing I would like to discuss is the information that you will need to provide on the FWA form. There are some major items that

will have to be provided, such as a name and address of the institution filing the FWA, the human protection administrator or reliable point of contact in the institution, and the institution's signatory official who actually signs the FWA.

The third item I would like to discuss is the listing of components. The listing of components is optional and, if you choose to list components, you should provide the name and location of the components over which the institution has legal authority that operate under a different name, that will be covered by the FWA.

For example, the John Jones Hospital may contain within it the Mary Smith Cancer Clinic, and if you wish to list The Mary Smith cancer clinic, it should be listed as a component of the John Jones Hospital.

The next item that needs to be provided is a statement of the ethical principles to be followed in protecting human research subjects. There are three check boxes: The Belmont Report, Declaration of Helsinki, and Other. If you check Other only, you must submit it to OHRP for review and approval of this particular document. It should be noted that if you do check just "Other" it will slow down the approval process.

And the next item on the slide represents the FWA institution's commitment to apply its FWA and the terms to nonexempt human subject research that is conducted or supported by any U.S. Common Rule department or agency, unless a Common Rule department or agency determines that the research will be conducted under a separate assurance.

This next slide applies only to U.S. institutions and it is optional. The option of voluntarily electing to apply either the Common Rule or the

Common Rule and subparts, B, C, D, and E of 45 CFR, Part 46, to all of its nonexempt human subject research, regardless of source of support, except for research that is covered by a separate assurance issued by another Common Rule federal department or agency.

The next slide refers to the institution's assurance to comply with the terms of the FWA or the Terms of Assurance, and in the first bullet, there is a URL for getting a copy of the Terms of Assurance.

Note: An institution's assurance that it will comply with the terms of the FWA whenever it engages in research in which its FWA applies means, for example, whenever the institution relies on an IRB operated by another institution or organization for review of research to which its FWA applies, that reliance arrangement is documented by a written agreement between the FWA institution and the other institution or organization operating the IRB.

The reliance agreement outlines the two entities' relationship and includes a commitment that the IRB will adhere to the requirements of the institution's FWA.

OHRP's sample IRB authorization agreement may be used for such IRB reliance arrangements or the two parties may develop their own agreement. This agreement must be kept on file at both institutions and made available to OHRP upon request but not sent OHRP, as some organizations do.

And the second bullet has to do with non-U.S. institutions. They must comply with at least one of the six listed procedural standards or other standard for the protection of human subjects that's recognized by the Common Rule departments and agencies. The six listed standards include the Common Rule, FDA regulations at 21 CFR, Parts 50 and 56, the current International

Conference on Harmonization, E-6 guidelines for good clinical practice, CIOMS, et cetera.

The next item has to do with the designation of IRBs. As of June 20, 2011, the policy actually changed. To reduce the burden, you no longer have to list all of the IRBs reviewing on behalf of an FWA institution on the FWA form. Now you only have to list all of your institution's internal IRBs; or if the institution does not have any internal IRBs, only one external IRB need to be designated. If the institution relies on multiple external IRBs, then designate the external IRB that reviews the largest percentage of the research covered by the FWA.

Note: An IRB reliance agreement with each external IRB is still required.

The next items that will have to be provided are the name and contact information for the human protection administrator -- also referred to as the HPA who is the person who serves as the institution's primary point of contact. Also needed are the name, contact information and the signature of the official authorized to represent the institution, identified on the FWA as the Signatory Official. The Signatory Official must assure that human subjects research to which the FWA applies is conducted in accordance with the Terms of Assurance.

Please note that the signatory official must be the senior official with the authority to sign, not on just behalf of the research but on behalf of the entire institution, because it is the institution that is making the legal promise or assurance that HHS supported research will be conducted in accordance with the federal regulations to protect the rights and welfare

of the subjects, in 45 CFR part 46.

This concludes the information that is required on the FWA form.

The next series of slides represent some commonly asked questions and answers, and the first question that is commonly asked is: Can an institution track OHRP's receipt of its FWA submission and its status? And the answer is yes, by going to the URL that is provided on the slide.

Here an institution will find information about when the FWA was received and which OHRP assurance coordinator is reviewing its application and how to contact that person. Of note, at OHRP, coordinators are assigned FWAs to review by the computer.

The second commonly asked question is: How will an institution know its submitted FWA application has been reviewed and approved by OHRP? The Human Protections Administrator, Signatory Official and the person that submitted the FWA application, will each receive an automatically computer generated e-mail notifying them that their FWA has been approved.

In addition, a PDF copy of the approved FWA will also be attached to the e-mail, and the e-mail will also contain the FWA number and when the FWA will expire.

The third commonly asked question is: When must an FWA be updated or renewed?

An institution must update its FWA within 90 days after the legal name of the institution, the human protections administrator, or the signatory official changes. FWA approval is effective for five years and must be renewed every five years, even if no changes have occurred, in order to maintain an active FWA.

Any FWA renewal or update electronically submitted to and approved by OHRP begins a new five year effective period.

I would like to pause again and take another poll to get an idea of how many of you remember how many institutions "checked the box." We will take a pause here to do this. You have one of three choices, 33%, 66% or 75%.

Okay. That's really good. The correct answer is 66%, and as you see, 86% of you got the right answer, so obviously everybody is paying attention. That's great.

The last thing I would like to provide you with is some information about resources, and this slide has on it the URL that will take you a FWA and IRB Registration resource site on our website. The next slide. will show you what that resource site looks like.

This resource site includes information on when an FWA is required and when an institution needs to register its IRB, a graphic and text decision tree to help decide if your institution needs to register its IRB or obtain an FWA, the URL for the Electronic Submission System (ESS) where you can electronically submit your IRB registrations and FWA submissions. In addition, Frequently Asked Questions (FAQs) on the FWA and IRB process are also posted in various places on our website.

And this last slide contains general contact information, and information on how you can join OHRP's LISTSERV, if you wish to receive announcements that OHRP sends out.

This concludes our webinar. Thank you for attending.

(Webinar concluded).