

Interview

Interview with Dr. Elyse I. Summers, President & CEO, and Dr. Sarah H. Kiskaddon, Director of Global Development & Public Affairs, Association for the Accreditation of Human Research Protection Program (AAHRPP) — Recent trend of human subject protection system in the U.S. and in the world —*¹

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Abstract

This is a record of interview with Dr. Elyse I. Summers, President & CEO, and Dr. Sarah H. Kiskaddon, Vice President, Global Development & Public Affairs, Association for the Accreditation of Human Research Protection Program (AAHRPP) in June 2015, and following discussion through the process of construction of this interview article.

Recently, an increasing number of institutions that conduct research involving human subjects are getting accreditation by AAHRPP. AAHRPP accreditation system is for the whole institutional program for human research subject protection, not limited to IRB (institutional review board) or EC (ethics committee). Recently the trend of research communities in the United States (U.S.) and some of Asian countries such as Korea and Taiwan is shifting from “IRB-oriented” to “HRPP-oriented” human subject protection.

AAHRPP is a non-governmental, not-for-profit organization, keeping partnership with government. Although their accreditation is not legally-obligated process, it is well-acknowledged assurance of compliance with governmental regulations, and as a result, it works as a proof of trust-worthy institutional practices. Also, recent trends in the U.S. and in some Asian countries shows that pharmaceutical companies prefer to work with AAHRPP-accredited institutions; and the “single IRB approach” for multi-center research seems to promote reviews at AAHRPP-accredited institutions.

In Japan, a new law for clinical research is going to be enacted and some institutions are interested in AAHRPP accreditation. In this context, it is a good opportunity for the Japanese research community to discuss more about HRPP-oriented human subject protection and the possibility of getting international accreditation of HRPPs, such as AAHRPP.

Key words

Association for the Accreditation of Human Research Protection Program (AAHRPP), institutional review board (IRB), ethics committee (EC), research ethics, quality assurance

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Elyse I. Summers, J.D., President and CEO

Ms. Elyse I. Summers is AAHRPP's second President and CEO. She provides strategic and substantive leadership and oversight on all aspects of AAHRPP's operations and is looking forward to leading AAHRPP well into the 21st century as the indispensable global organization for the accreditation of human research protection programs.

Ms. Summers was most recently the Director of the Division of Education and Development at the Office for Human Research Protections, a position she had held since January 2008. Ms Summers began working for OHRP and its predecessor, the Office for Protection Research Risks (OPRR), in 1998 in the Division of Compliance Oversight before moving to the Division of Education. Prior to joining OPRR/OHRP, Ms Summers practiced law pertaining to food, drugs, and other medical products. She offered guidance and counseling on Federal regulations and ethical issues related to the conduct of biomedical research. Ms. Summers spent five years before that time in the Office of the Commissioner at FDA, as Special Assistant to the Deputy Commissioner for External Affairs, and later as an original staff member of FDA's Office of Women's Health.

Ms. Summers has spoken extensively and published several articles and book chapters on biomedical and behavioral research and human research protections. She has also practiced the law of tax-exempt

organizations, and has spoken and written on that topic as well. At the start of her professional career, Ms. Summers represented research universities at the Association of American Universities. She earned a J.D. from the George Washington University National Law Center and a B.A. from the University of Michigan. She is a member of the Bar of the District of Columbia and of the Commonwealth of Pennsylvania.



Sarah H. Kiskaddon, J.D., M.A., Vice President, Global Development and Public Affairs

Ms. Sarah H. Kiskaddon oversees global development and educational programming for AAHRPP clients, as well as the larger research community on behalf of AAHRPP. She is responsible for new business development, AAHRPP communications, and public affairs. Ms. Kiskaddon oversees the content of AAHRPP webinars and annual conference, as well as serving as the general editor of the quarterly *Advance* Newsletter.

Ms. Kiskaddon is an attorney and served for over 10 years as the director of the Human Subject Protection Program at the Connecticut Children's Medical Center where she oversaw the accreditation process. She also served as vice-chair of the IRB and held a faculty appointment at the University of Connecticut. Prior to that, she was employed at Yale University where she was director, and vice-chair, of the Human Investigation Committee. She has also served as the executive director of the IRB at the New York State Psychiatric Institute affiliated with Columbia University. She has published original research and lectured extensively on research ethics, primarily focusing on special protections for children. Ms. Kiskaddon was a site visitor for AAHRPP from 2009 to 2012.

Source: AAHRPP web-site: <http://www.aahrpp.org/learn/about-aahrpp/senior-staff>

1. Introduction: increasing AAHRPP-accredited institutions in Asia

Interviewer Thank you so much for your acceptance of today's visit and this interview. The reason why I visit AAHRPP (Association for the Accreditation of Human Research Protection Program, Inc.) is that I believe that a recent trend for human subject protection systems is shifting from just focusing IRB (institutional review board) or EC (ethics committee) to a "program" of human research protections, which we call "HRPP (human research protection program)". I learned much from people in Korea and Taiwan who are engaged in their programs of human subject protection. Several institutions in Korea and Taiwan have gotten accredited but in Japan at this moment there is no organization accredited, although some institutes are now preparing to apply. I several times count the number of

AAHRPP-accredited institutes, updating at each opportunity to have lecture on this topic (Table 1. Last updated at the time of this publication). Also I visited some of AAHRPP-accredited institutions in Korea and Taiwan and observed their IRB meetings (Table 2). As these countries are close to Japan I have plenty of opportunities to visit them for invited lectures or to invite some of these people to Japan. After studying the actual situation of institutions that received AAHRPP accreditation, now it is great opportunity to be able to visit you, here at the office of AAHRPP.

In Japan, a new law to cover clinical research is going to be established (in April, 2017. Fig. 1). In 2014, new ethics committee (EC) accreditation system started and a small number of ECs got accreditations. In such situation, some of Japanese institutions are preparing for AAHRPP accreditation. Because some of Japanese institutions are very much interested in AAHRPP, so first I would like to ask you to provide brief introduction of your organization.

Table 1 Increasing number of AAHRPP-accredited institutes in the world

	Sept, 2013	Aug 23, 2015	Nov 8, 2015	Aug 26, 2016	March 30, 2017
USA	172	181	186	189	192
South Korea	5	6	6	6	6
Taiwan	1	6	6	6	6
India	3	6	5	5	6
China	1	3	4	6	6
Singapore	1	1	1	1	1
Thailand	0	1	1	1	1
Japan	0	0	0	0	0
Canada	2	2	2	2	2
Mexico	1	2	2	2	2
Saudi Arabia	0	1	1	2	2
Brazil	0	0	0	1	1
Belgium	0	0	0	2	2
South Africa	0	0	0	1	1

Source: Association for the Accreditation of Human Research Protection Program (AAHRPP). Accredited organizations [last cited 2017 Mar 30].

Available from : <http://www.aahrpp.org/learn/find-an-accredited-organization>

Table 2 AAHRPP accredited institutes in Asian countries and IRB observation there

	AAHRPP accreditation	Visit by Kurihara	
		Interview	IRB observation
Korea			
Samsung Medical Center	Jun 2006	Dec 2014 Jan 2016	Dec 2014 Jan 2016
Severance Hospital, Yonsei University	Jun 2010	Sep 2013	
The Catholic University of Korea	Jun 2010	Sep 2013	Dec 2014
Seoul National University Hospital	Dec 2012	Aug 2012 Aug 2013 Jan 2016	Aug 2012 Jan 2016
Kyung Hee University Hospital	Sep 2013		
Asan Medical Center	Dec 2013	Aug 2013	
Taiwan			
National Taiwan University Hospital	Dec 2012	Aug 2012 Oct 2016	Oct 2016
Taipei Medical University Hospital	Mar 2014		
China Medical University Hospital	Dec 2014		
Changhua Christian Hospital	Mar 2015		
Taipei Medical University-Shuang Ho Hospital	Jun 2015		
Taipei Municipal Wanfang Hospital, Taipei Medical University	Jun 2015		

* As for Taiwan, IRB meeting at the Chang Gung Memorial Hospital, at the preparation status for AAHRPP, was observed in December 2016.

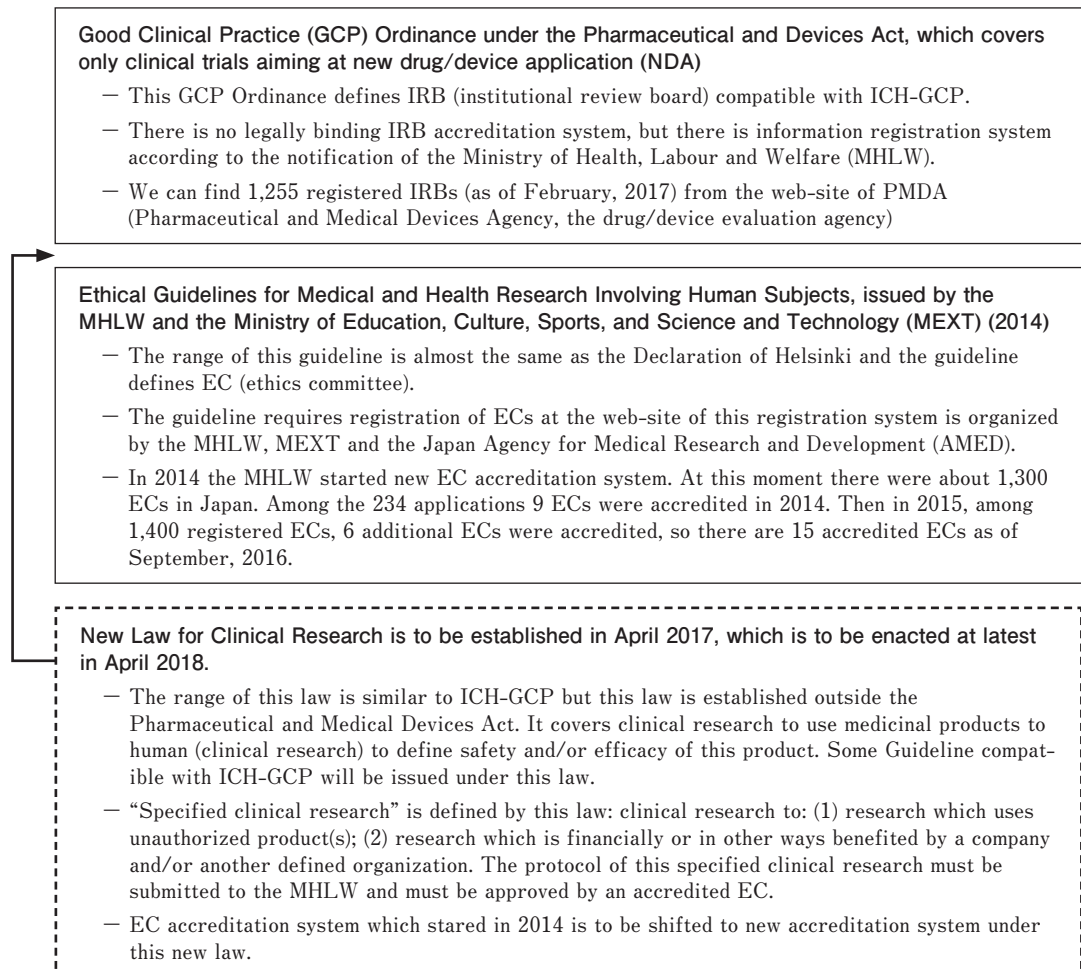
2. Establishment and development of AAHRPP

Summers We appreciate you for visiting us and we are happy to introduce our activities to a Japanese community that is interested in human subject protection programs. As you may know, around the late 1990s and early 2000s, there were several issues and problems arising from research involving human subjects and the protections in place at that time. The community of organizations that participated in human subjects’ research and those that oversee various aspects of the enterprise came together and decided that the community needed to take ownership of the issue itself.

So, several organizations, including the Association

of American Medical Colleges, the Association of American Universities (which represents the top research universities), the Association of Public and Land Grant Universities (which also includes very large state universities), an organization called COSSA (Consortium of Social Science Associations), another organization called FASEB (Federation of American Societies of Experimental Biology), and the National Health Council (which represents disease advocacy groups) – all of these organizations came together and decided that a peer model of accreditation was the way to go so that organizations – colleges, universities, academic medical centers and other research organizations – could get ahead of the issues and reign them in themselves. That led to the founding of AAHRPP in 2001.

Fig. 1 Situations of research regulations and IRB/EC qualification system in Japan, as of March 2017



In the United States, we have a very large cohort of NGOs (non-governmental organizations) that are tax-exempt organizations conducting charitable and educational activities in support of the common good. AAHRPP is a tax-exempt NGO. The AAHRPP accreditation process is completely independent from the government but substantively it's almost a parallel process, in the sense that part of the process of achieving AAHRPP accreditation includes ascertaining that an organization is compliant with its own government regulations. We start with the main bolus of regulation – whether they are domestic

U.S. or International Conference on Harmonization GCP or a particular country's laws and regulations – and we build out from there to ensure a robust HRPP.

Interviewer I think the government simultaneously developed the Federal Wide Assurance (FWA).

Summers Well prior to that time, there had been a system of assurances, but the U.S. federal government reduced many types of assurances to a single option, the FWA, which basically streamlined a process that had been much more complex.

Under the old system, large universities and academic medical centers could get what was called Multiple Project Assurance (MPA), but smaller organizations that might have just a handful of studies got single project assurances. They had to literally submit project by project to the federal government for approval of an assurance.

Kiskaddon The idea was the government wouldn't have to do crackdowns or wouldn't have to pass more legislations. We want to be responsible in the research enterprises. We want the public to trusts us. It's in our benefit to run it in a way that everybody respects and trust research and that we shouldn't rely on the government to make us do that. It's a peer reviewed process and it's educational.

Interviewer I agree that it is very nice that such voluntary process improves human subject protection system in each organization. One thing is that the Veterans Administration has made it mandatory that organization engaged in human research with their funding to get accreditation of

human subject protection program. Also they changed their designation of accreditation body from AAHRPP to another organization, Alion.

Summers The VA's contract with the other organizations was actually terminated a couple years ago for non-performance, so at the moment, I think the Veterans Administration is trying to figure out what to do with that going forward because there have been a lot of changes. In terms of the history of the VA's involvement with mandatory accreditation, there were some particularly egregious things that went on at a major Veterans facility in West Los Angeles in 1998 (<http://articles.latimes.com/keyword/west-los-angeles-veterans-administration-hospital>) So, as you might appreciate, whenever veterans are involved, the U.S. Congress is very heightened in its awareness and attention to that. So even though the case was one of many, that particular case did get the attention of Congress, and so Congress mandated it for that sector of research.

Interviewer Also central IRB became manda-



At the time of visiting AAHRPP office in June, 2015. From the left, Summers, Kurihara, and Kiskaddon.

tory for Veterans Administration’s multicenter trial*².

Summers Well, that’s actually newer. That wasn’t part of the original requirement or mandate. They’ve been looking at the central IRB review in the VA for quite some time now, perhaps 7 or 8 years. I think their desire is similar to what we’re seeing in a lot of sectors – that it’s more efficient to have one IRB looking at a study that will be conducted in the same manner at multiple sites.

Interviewer And what is the reason why they changed from AAHRPP to Alion? Alion is a company which is engaged in some kind of military techniques.

Summers As I mentioned above, their contract with Alion was been terminated for non-performance. The process here is that when a government agency needs services of any sort, they have to put out what is called a Request for Proposal (RFP). Both AAHRPP and Alion put in a proposal. I think Alion was selected on the basis of cost. But even though they were selected, many of the individual VA sites were still very happy with AAHRPP and they have remained with AAHRPP, and we still have several VA organizations that have stayed with AAHRPP accreditation.

Interviewer Is there any other organization that provides this kind of accreditation?

Summers Not that we’re aware of. At the moment and I think for the foreseeable future it will be just us; and I do think that because again, both domestically and internationally, we’ve developed now a process and a product that people are very comfortable with and which provides a global

standard.

Kiskaddon One of our priorities is to be transparent; our standards are up on our website. Everything that we do, you can find now in our website. And, when a client calls us, we are happy to work with them in a variety of ways, including on-line real-time seminars to help them go through the process.

3. Shifting from “IRB-oriented” to “HRPP-oriented”

Interviewer And for me it is surprising that there are some contact persons in Korea and Taiwan who are engaged in not only work for getting accreditation for their own organization but also provide education for other institutions in their country. Professor Ian Chen of Taiwan National University is one of those. He told me through e-mail that they are now shifting from an IRB-oriented system to HRPP-oriented system of human subject protection. In Korea, I have many friends working for HRPP, and heard that the government issued in 2014 guideline for HRPP, without being satisfied with their IRB accreditation system*^{3,4}.

Kiskaddon I’m really excited about that. The AAHRPP concept, which people didn’t understand at the beginning, is now understood and appreciated. We were talking earlier about how these experts have started to really embrace AAHRPP especially in Asia. It’s starting to happen a lot in America and in Middle East. But Asia and in particular Taiwan, China, Korea and Singapore, have

*² Later on, central IRB (now called “single IRB”) became mandatory for multicenter trial granted by NIH (National Institute of Health), and then it became mandatory for any federal-funded research covered by the U.S. Common Rule for human subject protection (45CF46).

*³ Kurihara C, Younjin R. On the Korean Guideline for Clinical Trial and the Human Subject Protection Program. *Rinsho Hyoka (Clin Eval)*. 2017; 45(1): 81-5.

*⁴ Younjin R, Kurihara C, trans, Occupational Guideline for Clinical Trial Human Research Protection Program. *Rinsho Hyoka (Clin Eval)*. 2017; 45(1): 87-90.

completely embraced it.

Interviewer They are also very much interested in the JCI (Joint Commission International) accreditation.

Summers Yes, exactly. From my view, it's very complementary to AAHRPP. Their processes are similar to AAHRPP. These are processes that are recognized around the world.

Kiskaddon The same types of places – one excels in their clinical care and the other one in clinical research.

Interviewer I understand very well the difference between IRB-oriented and HRPP program-oriented, but I would like to ask you how you describe HRPP-oriented approach.

Summers As you've suggested, historically, I think everyone thought of this institutional review board as being the focal point and the repository of all the knowledge and information and everything having to do with protecting the volunteers who make the enterprise (clinical research) possible. But as we move more into the 21st century, the community and our Institute of Medicine (IOM), our National Academies of Sciences (NAS) all recog-

nized that there are really so many different parts to the system that it's not just the IRB. It's the compliance office, if it's a separate office. It's the education and training group. It's your legal counsel. It's the pharmacy, if you're dispensing investigational drugs. So there was a growing awareness that there are many places across an organization that really touch upon a person's participation and their safety and welfare (Fig. 2). So that concept actually had really been embraced around the world.

Kiskaddon The Institute of Medicine did a report in the year 2000 called "A Shared Responsibility" and there's this person that I met who wrote on the subject of human subject research protection program that IRBs were suffering under what we call "mission creep" – that they have too many things to do.

So the Inspector General's office looked at IRBs and said they're so distracted with other matters, such as education and conflict of interest, that they barely can do their review function. And they recommended that IRBs be used to review protocols, and that the institution share the responsibility for

Fig. 2 Human Research Protection Program (HRPP)



Provided by AAHRPP

all the other things that affect the safety of participants.

I wasn't here at AAHRPP at that time, but we've very much used that term – Shared Responsibility – and I think AAHRPP spread the term. The IOM used that term to say that, "You know you don't have to have the IRB do everything." In fact, many of the things that happen in clinical trials that hurt participants don't happen at the IRB review or some things they are ignoring. For example, what is in the clinical trial agreement is important (i.e., the contract). But now we have the standards on the contract, the clinical trial agreement has to say certain things. When I was IRB director I've seen a lot of problems but I've never seen the problem be that the IRB didn't do a good review job. The problem is somewhere in the organization – the reporting requirements of an investigator, for example. Those kinds of things need to be robust. So I actually think this should be much stronger than just focusing on an IRB review.

Interviewer Yes, I think so, too. In 2015 in Japan, clinical research guideline, which is outside the Pharmaceutical Affairs Law and GCP, was revised and monitoring and audit requirements came to be included. Then we found that even if a protocol passed ethics committee review, not all the things written in the protocol is not always adhered. Monitoring and audit is just a part of a whole program of human subject protection. But it is a very big change in Japan. However unfortunately at this moment in Japan only small number of people are considering whole the system of HRPP is important, not limited to IRB/EC review. Now in Japan the system is divided independently into small pieces, not well organized as a whole.

Summers We actually think that one of the great benefits of the accreditation process is that it not only encourages, it actually forces the silos to break down and for different parts of an organi-

zation to communicate with each other. Because the process itself is very transparent and it forces organizations to be more open, all to the benefit of volunteers, the participants.

Interviewer I read through the evaluation instruments and I think most of the elements there are already in the regulation.

Summers Right. As you may know, U.S. regulations, at least the OHRP's 45CFR46 regulations are about 18 pages long. On that point I think the AAHRPP elements, particularly as described in the Evaluation Instrument, do a good job in fleshing out the spirit of what's behind those regulatory sentences.

Kiskaddon When you talk about auditing and monitoring, we have a standard that the HRPP has to monitor itself or have some monitoring and quality improvement done. Those kinds of things are not in the regulations.

An example of another AAHRPP standard that exceeds the regulations is that we ask – "If your sponsor is monitoring the investigators, the IRB should be able to get that report." Or "if a data safety monitoring board has been appointed by the sponsor, the IRB should be given a report of that safety monitoring board." That really changed things. When I was an IRB member, I never used to see those reports. It used to annoy me at that time. For example, a data safety monitoring board has been appointed, but I didn't know about it. I don't get their reports. But then after we required this in our hospital, we did get them.

4. How to get accreditation

Interviewer Actually, how is the first step for this accreditation process? In the document it says we should describe the evaluation elements, the self-evaluation. For example, we should write that we have kind of SOP, and others.

Summers Well, you do your own self-assessment but you can simultaneously work with us. For people who have not submitted anything yet, I recommend that they do it the way you've just described it which is to go through each of our elements, and make a note where a policy may be missing or lacking in some way.

The narrative portion to our application is very short, a maximum of 7 pages. Once you've gathered all the documents then all you have to do is attach all your documents. So where you have those policies, you don't have to rewrite them. You have already done your self-assessment, so you just attach them. And then you attach an index in front of it so we can find them. For example, the index says "policies related to IC can be found on page 12" and you hyperlink it.

Usually, an organization cites to an SOP. However, in certain contexts there are a couple of elements for which you can give a descriptive answer. For example, if you do not do "transnational research", if you don't do research outside your country then you can skip it, and you can say, "Not Applicable." Alternatively, if you don't have a policy on something required, you would have to write a policy. That's where most of the work is. That self-assessment usually takes about 6 months at least. Once you've done that, putting it in the application including writing in the application form is not very time consuming.

Interviewer And then the next step is you go for the site visit and see how this is actually implemented?

Summers Exactly; how the practice corresponds with the policies, yes.

Kiskaddon Because some of the processes are going to be new, you write them as part of the application for self-assessment. Sometimes we find that those new ones are not as familiar so you need to do some training with your investigators and

IRB members so that they can say, "Yes, we understand and follow these procedures."

Interviewer I asked some of the accredited institutes in Korea and Taiwan how they tackle the problem of language. Did all these institutes provide translations of all their SOPs?

Summers Yes.

Interviewer I heard that you're thinking about appointing some counterpart for local site visits.

Summers It's something we talk about a lot.

Kiskaddon We do have several international site visitors, including one from Korea, one from Taiwan, and two from China.

Interviewer After you have designated a counterpart in a specific country, is it possible for that country to apply without making English translations of their SOPs and documents?

Summers At the moment, our council on accreditation is populated by English speakers only. But we are open to exploring new avenues in the future.

Interviewer Language would be a bit of a problem for Japan for a couple of reasons. For one thing, it is very rare for organizations in Japan to have bilingual staff like in Korea or Taiwan. It seems that Japanese people are very much stuck to Japanese language. Additionally, Japanese regulations are very much complicated, and it is hard task to make English translation.

Kiskaddon We always do an addendum to our evaluation for each country. So if we have a new country in which we've never done an evaluation before, or when we first hear of a country that want to apply for accreditation like with Japan, we do an addendum for that country. For example, we would research Japanese laws that relate to the research and we put it up on our website and it's indicated by the country's flag on our website. Right now we're pleased to say have about 10 or 12 flags there. And you can see that we add on certain regulations to our accreditation centers that match

to our laws. You don't have to have everybody on site speaking English because when we go there they usually provide a translator.

Summers During my trips to the RERF (Radiation Effects Research Foundation) in Hiroshima, mostly everybody there of course spoke exclusively Japanese. We just had a translator during the discussions, and it worked very well. Everything went smoothly.

When we visited the RERF, we were very impressed with their adherence to the different guidelines and laws. There were some areas in which the Japanese laws were even more advanced than the U.S. laws in the sense that certain areas like in terms of privacy and data, specimens, and things like that, they had a really very sophisticated framework.

Kiskaddon The organization does not have to follow U.S. regulations. I always remind inspectors on this point. Some applicants want to get NIH funding or they want to collaborate with universities here that have NIH projects; in that case they do have to follow US law. But if there's not going to be funding from or interaction with a U.S. regulatory body, they don't have to follow U.S. FDA but they will have to follow their own country's FDA regulations.

5. Incentives to get accreditation

Interviewer The most important point for Japan is actual incentive for accreditation. For example, I asked people in Korea and Taiwan why their institution made the decision to get accreditation. There is of course ethical reason of protecting research subjects. But the actual reason is that if you get the accreditation it is possible to induce global companies to do clinical trials in the country, and pass the FDA's inspection.

Kiskaddon Yes, that's right. When we're doing

a presentation, we even openly say there are two reasons. One is you want to know that you are compliant. Secondly, you want to stand out to sponsors and others as a high functioning program. I mean, business interest and doing the right thing coincides, especially since more sponsors now, like Pfizer, are thinking of accreditations. Pfizer has said in open forums that they will always have an AAHRPP-accredited IRB review on every study. So if they conduct a trial in some country they need to find an accredited IRB or they develop one IRB for themselves that is accredited.

There's one site called ViS (<http://www.visresearch.com/servlet/Controller>). It's a clinical trial planning tool for sponsors and others. They provide an online feasibility platform that streamlines the process of finding and assessing researchers and research centers for clinical trials. They have a globe that tells you how many patients a clinical trial site has in each category of disease; what kinds of research they do; and whether they're AAHRPP-accredited.

I'm always looking for data to find out how much this accreditation is influencing sponsors' decision. I do have U.S. data showing that FDA inspections come out better at AAHRPP-accredited sites. We have data from 2008 and 2012 on the number of inspections of clinical investigators, the findings, and whether they had any negative findings at AAHRPP sites. It's incredibly different from non-accredited sites (Table 3). Just now we are working to update this data. There's pretty strong evidence. For example, if you looked at last year's FDA warning letters, out of 37 to IRBs, only one of them went to an AAHRPP-accredited organization.

Kiskaddon I think the reason why AAHRPP worked was because it came from the research community. For example, India now has its own accreditation process. It's brand new. And some of India's new clinical trials laws regulations have

Table 3 Clinical investigator findings – 2015

Type	No Action Indicated	Voluntary Action Indicated	Ordered Action Indicated	N
AAHRPP Accredited	61%	38%	0%	18
Non-accredited	61%	33%	1%	68
				86

Provided by AAHRPP

been very difficult for sponsors to understand and implement.

Interviewer Do you think that is because there were some big scandals in India?

Kiskaddon Yes, that’s what led to all of this.

Summers It’s not uncommon to see the regulatory pendulum swing broadly when there is either the perception or reality that individuals were harmed in the context of a research study. This is even more the case in under-resourced areas where people are justifiably concerned that their population not be taken advantage of. That is what happened in India.

6. Electronic IRB and central IRB

Interviewer Just one more question. How do you think about “electronic IRB (e-IRB) system, from the perspective of human subject protection?

Kiskaddon It’s moving in that direction. In the conference today, we had a couple of presentations on how it is easier to do compliance with their electronic systems so they can search things and keep track of compliance issues. But I would still say probably a quarter or maybe even a third of our IRBs, because they are smaller, are still doing paper review even though they have a database.

Interviewer When I saw the discussions of IRBs in Korea using e-IRB system, I’ve observed that it’s not only efficient to use the e-IRB system

but by means of their e-IRB system their discussion is focused on the risk-benefit evaluation.

Kiskaddon That’s good. I’m glad to hear that because that is what we hope. We’re trying to get people not to think about everything, but to think about the approval criteria that are important.

Summers Yes, we believe that some of NCI’s (National Cancer Institute) processes related to their central IRB were refined in a beneficial way through the process of their AAHRPP application and obtaining AAHRPP accreditation.

Kiskaddon I think that NCI, as well as NIH would never have come out with that policy to facilitate central IRB unless they were accredited, and that’s an issue with collaborations. Once they are accredited, they do not necessarily want to see the review go to an unaccredited place. So they sometimes have it in the collaboration agreement that everybody must be AAHRPP-accredited. So if you’re going to have a central IRB review, you should know that their policies are strong. The best way to know that is if they are accredited.

Interviewer Is there any standard to evaluate the central IRB to get the information from the other centers?

Kiskaddon Yes, they have. The local context has been a big issue. Central IRBs are independent IRBs. They need the CVs of the investigators. They need to know that those investigators are not going to be non-compliant. They need to know

something about the community that they are in. AAHRPP has a tip sheet on what you should find out from the other IRB (https://admin.share.aahrpp.org/Website%20Documents/Tip_Sheet_24_Relying_on_An_External_IRB.PDF).

Interviewer It would be nice for Japanese IRB/ECs to learn about it. Thank you so much for today's valuable discussion and I believe more and

more Japanese research community would come to be interested in HRPP-oriented human subject protection and establish more effective research governance framework. Therefore, this interview will be valuable for all of these people seeking for the way of improvement.

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