

**Informed consent for: “The ethos and effects of data-sharing rules: Examining the history of the ‘Bermuda principles’ and their effects on 21<sup>st</sup> century science”**

**University of Adelaide**

**Duke University**

Researchers at the University of Adelaide, Australia, and the IGSP Center for Genome Ethics, Law & Policy, Duke University, are engaged in research on the **Bermuda Principles** for sharing DNA sequence data from high-volume sequencing centers. You have been selected for an interview because we believe that the recollections you may have of your experiences with the International Strategy Meetings for Human Genome Sequencing (1996-1998) will be interesting and helpful for our project.

We expect that interviews will last from 30 minutes to much longer, but you may stop your interview at any time. Your participation is strictly voluntary, and you do not have to answer every question asked.

Your interview is being recorded and we may take written notes during the interview. After your interview, we may prepare a typed transcript of the interview. If we prepare a transcript, you will have an opportunity to review it and to make deletions and corrections.

Unless you indicate otherwise, the *information* that you provide in this interview will be “on the record”—that is, it can be attributed to you in the various articles and chapters that we plan to write, and thus could become public through these channels. If, however, at some point in the interview you want to provide us with information that might be useful for us to know, but which you do not want to have attributed to you, you should tell us that you wish to go “off the record” and we will stop the recording. We will, however, take notes for our own use. When you are ready to go back “on the record,” we will resume recording. Anything you say while “off the record” will not be on the audio recording and therefore will not appear in the transcript.

All *materials* from your interview (audio recording; transcript; interviewer's notes) will be available only to members of the research team affiliated with this project, unless you consent to their wider use, as described in the paragraph below. The digital materials will be maintained in a secure, HIPPA-compliant drive at Duke University. The paper materials will be stored in a locked cabinet.

In addition to the scholarly articles and chapters that we plan to write, we also hope to create a resource for other scholars and members of the public. We plan to post some of our research data to online digital archives. While we will use your “on the record” comments to inform and write our articles, we will not post your interview transcript or audio recording online unless you give us permission to do so, in a separate agreement. At the time we send your transcript to you for review, we will also provide a consent form asking your permission to post your interview transcript and/or audio recording online. The form will provide you with different options for how, when, and with whom the materials may be shared. You will, of course, also have the option not to share the materials beyond the Duke and Adelaide researchers.

One risk of this study is that you may voluntarily disclose identifiable information that later could be requested for legal proceedings, or otherwise be used against you. Please take this into consideration when you are speaking. There may be other risks associated with your “on the record” views being made publicly available, such as having your views mischaracterized or misunderstood.

The main benefit of participating in this study is ensuring that your side of the story is properly portrayed in this history of the Bermuda Principles, which have become a model for open and collaborative research in genomics and other fields.

To help us protect the privacy of those parts of your interview that are not public, we have obtained a Certificate of Confidentiality from the U.S. National Institutes of Health. With this Certificate, we investigators cannot be forced to disclose information that may identify you, even by a court subpoena, in any U.S. federal, state, or local civil, criminal, administrative, legislative, or other proceedings. We researchers can use the Certificate to resist any demands for information that would identify you.

The Certificate cannot be used, however, to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person or institution obtains your written consent to receive research information, the researchers may not use the Certificate to withhold that information.

Signature   
Printed Name Yoshiyuki Sakaki  
Date Dec. 1, 2011

*If you have read this form in its entirety and agree to the interview and its terms, please sign and date above.*

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*If you have any questions about your rights as a research subject, you may contact the **Duke University Institutional Review Board** at 919-684-3030 or [ors-info@duke.edu](mailto:ors-info@duke.edu).*

PLEASE FILL OUT AND RETURN THIS FORM TO: Center for Public Genomics, Duke University; c/o Susan Brooks; Center for Genome Ethics, Law, and Policy; 304 Research Drive, Box 90141; Durham, NC, 27708. OR: You may fax it to us at (U.S.) 1-919-668-0799.

**Interviewee Information.** Please list an address where we can contact you.

Full name: Yoshiyuki Sakaki Date of interview: Dec. 2, 2011  
Current institutional affiliation: Toyohashi University of Technology  
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**Interviewer Information.**

Full name(s): \_\_\_\_\_  
Affiliations(s): \_\_\_\_\_

I, the undersigned, have read the above, and I **AGREE** to release my interview materials, subject to any restrictions listed below:

(A)  I place **no restrictions** on my interview materials.

OR

(B)  My interview materials may be reviewed, used, and quoted by the researchers affiliated with the Center for Public Genomics, Duke University; and in addition (check all that apply):

Researchers unaffiliated with the Center for Public Genomics may read the interview transcript and any related documents only after obtaining my permission.

Researchers unaffiliated with the Center for Public Genomics may quote from the interview only after obtaining my permission.

Researchers unaffiliated with the Center for Public Genomics **DO NOT HAVE** my permission to read or quote from the interview.

**Posting interview materials to public digital archives:** In spite of any restrictions listed above, I give permission for my interview materials to be made publicly available on the Internet by deposit in an institutionally affiliated archive:

1 year from the date of this form

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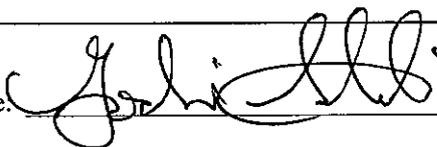
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Date: April, 6, 2012

Interviewee: Yoshiyuki Sakaki

Date, location, method: 01 December 2011, Durham, NC, by phone

Interviewers: Kathryn Maxson, Robert Cook-Deegan

BCD: So [KM] is about to turn on the tape, and explain what our process is going to be. We will do this interview. We won't ask the questions exactly in order. We'll ask you questions and kind of see where it goes. And at the end of the interview we'll send the tape off to be transcribed into written form. And then at some point in the next couple weeks we will send you, you can either get it by e-mail or drop box or hard copy version. We'll send it off to you and it will come with a form of what you would like us to do with it that you can send back when you've gone through and edited out anything that you want to remove or revise or whatever. And what we will do is, we will take the written document and we will make that available under the conditions that are on this check sheet. So it ranges from everything from this is perfectly okay to share publicly with anybody right now, to don't ever share it with anybody ever except for yourselves. And all sorts of options in between, like share it with scholars or share after a year or two years or whatever.

YSakaki: Yeah, okay.

BCD: So you can expect to get another document from us based on this interview within a couple weeks.

YSakaki: Okay.

BCD: So if you could start off by just kind of telling us why you were invited to the Bermuda meetings and what you saw as your role going into them. Just the stuff that comes to mind first for why you were there and how you perceived the context for these meetings starting in 1996.

KM: Well, I think [YSakaki] was only there in 1998. Is that correct?

YSakaki: Yeah, I missed the meeting that was in 1996. I was also invited to the 1997 meeting, but I could not attend because of a skiing injury.

BCD: Okay, so for whatever meeting, just place yourself in the context and explain why you would have been invited, what your role was and what your expectations were and what the outcomes were and things like that.

YSakaki: Since 1995, I had been a leading researcher and representative of the human genome sequence project, supported by the Japanese government. Also I was the Japanese representative of the human chromosome 21 sequencing consortium, which was mostly organized by the Japanese and the German groups. And for those reasons, I think I was invited to the Bermuda meeting in 1998.

KM: So what were your impressions going in that the purpose of the meeting was? What did you think was going to get done there and had there been any indication, either formally or otherwise, what the purpose of the meeting was? I know this

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was the last of three meetings so perhaps this meeting was just going to be like the other two. But how did it feel like going in?

YSakaki: It was long time ago, so I'm not sure I can answer the question precisely. Anyway let me try. About the first meeting, I saw the document and some report from our Japanese representative, Dr. Ogasawara. And at that time my understanding was that the people at the meeting had discussed some very basic principles for the international consortium. And I'm not really sure whether at the 1996 meeting already Bermuda principle was approved or not. But anyway, I think the international consortium had basically accepted the spirit of the Bermuda principles. So in the 1998 meeting I expected to confirm some principles from the practical viewpoints. I did not know that at the 1998 meeting, the United States groups and the U.K. groups would propose expansion of the Bermuda principles to other organisms or other projects. Since that was an unexpected issue, I was a bit surprised and I thought that it was beyond my position representing Japan as a human genome researcher.

KM: So when you got there, what was the mood like or the tenor like? What happened? Was it a primarily scientific meeting in 1998, or was there more discussion of policy issues? Or was it more scientific coordination?

YSakaki: Initially I thought it was a more scientific meeting to discuss the practical issues, about how we coordinate or how we treat the data, so on. But to my knowledge, still this 1998 meeting was pretty much focused on the principles, in particular for non-human organisms. I understood the argument as an individual scientist. But as a person representing the Japanese human genome project, I couldn't give agreement to the discussed proposals that is, the expansion of the principle to other organisms. It was beyond my responsibility. On the other hand, of course, many human genome scientists joined there. So I could discuss many practical issues in the informal places, but in the formal meetings it was a little bit different from my expectations.

KM: And you said that as a representative of Japan you couldn't say anything that would be representative of Japan as a whole. You could only affirm these principles as an individual scientist. So I'm interested in the policy framework that you were working with. Could you describe a bit about the stance of the Japanese government towards this sharing of data at the time?

YSakaki: I represented Japan in Human Genome Project (HGP), but not the Japanese Government nor the scientific community. The Bermuda principle was very different from the traditional researchers' principles. It was understood by Japanese scientific communities or even the funding agencies because it was the principle in this particular very international project. And the HGP was very clear and beneficial for the medical sciences and eventually human beings. So those are the reasons the Bermuda principle was supported in Japanese communities.

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International contribution is a very important 'key word' to be supported in Japan. But if we extend these kinds of principles to the other projects or other organisms, the situation is quite different. Each funding agency or each researcher is doing work for their own purposes or their own benefit, completely different from the goal or purpose or style of the human genome project.

BCD: So you were coming to these meetings basically as a working scientist to meet with the other folks who were actually doing sequencing and running labs that were internationally similar to yours.

YSakaki: Yes.

BCD: Were there ... from Wellcome Trust and from NIH, there were also some administrators from the funding agencies? Were there any administrators from STA or Monbusho or any of the funding agencies?

YSakaki: Yes, Mr. Kikuchi was invited from JST, that is one of the funding agencies under the control of STA (Science and Technology Agency). Actually, he was in the position of coordinator for the program in Japan. To my understanding, he was not in the position to represent Japan to make any decision. So he could describe the current situation or current understanding of the funding agencies. But he could not say anything beyond that. So unfortunately, Japan had no official there who can say anything beyond some domestic agreement. And also I was invited as leading the human genome project in Japan. So I had some right to describe something about human genome project. But beyond that, I had no right to say anything conclusive about Governmental policy.

BCD: And did you know or could you predict or know ... and from what we understand from some of our other interviews ... is the positions of the Japanese and German governments, there was some tension in the air about the open disclosure policy and some uncertainty about whether the folks at the meeting could actually speak for what the official government policy was. How did you think through that as one of the people trying to get the work done? Did you feel like you had the authority to make decisions there and set policy? How did that feel to you as one of the few scientists from Asia at this meeting?

YSakaki: Okay, first, I have to say again that Japanese and German colleagues who attended the Bermuda meeting were essentially the scientists leading the HGP in each country. Generally speaking, Japanese science policymakers or funding agencies had pretty much different views or policies from the Bermuda principles. They had the traditional principles for funding. [*\*\*KM: These traditional principles would be, releasing scientific data at the time of publication.\*\**] But even so, this human genome project was so international and so important for the future, that some high authority people in Monbusho and STA understood it as important for Japan to participate in this project under the agreement of the

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international consortium, that is, the Bermuda rules. So the Japanese government did not support the Bermuda principles in general. The HGP was exceptional because of its truly international cooperation. So you can imagine we were in a delicate position to get support to continue the project.

BCD: Yeah, I just wondered how it felt to you. And I'm vaguely remembering that Japan had just in the mid-1990s, had begun to implement its version of the Bayh-Dole Act, giving universities the authorities to get patents and intellectual property. And there was a big push for commercial applications of biotechnology. And I was wondering if there was any interaction between the discussions that were going on in Japan about commercialization of the biological sciences and how this particular very unusual project was being handled because of its international character and its kind of public works project aspects.

YSakaki: The Ministry of International Trade and Industry (MITI) has made large investment to national benefit projects, and they started so-called cDNA project towards the hunting of useful genes. We had no fund, no support from MITI. We were afraid that we were forced to industrial application. Fortunately, Monbusho and STA showed understanding to the human genome project as the basis of medical sciences and also international contributions.

BCD: And did you expect to get any ... when you went away from this meeting in 1998 and basically the Bermuda rules were restated and published again afterwards, did you expect anybody to complain to you from the government, or did you feel like you had the authority to make whatever decisions you needed to make to participate in this international project?

YSakaki: I think by 1998, for the human genome project or human genome sequencing, the people recognized it as important for international contribution. So even if the Bermuda rules were published people did not say anything against the human genome project, but beyond human genome sequencing, I think probably no one considered this statement could be applied, or for other projects.

BCD: So you basically expected to have a special set of rules for open disclosure, rapid data sharing, for this project, but that would not necessarily be what would be expected in other kinds of science? Is that what you're saying?

YSakaki: Right, I should say this is a basic attitude of the Japanese scientific community at that time. But also at the same time, I should say our continuous message about the importance of the human genome project gradually changed the minds of some Japanese scientific communities. They began to consider some very big framework, or basis for future sciences and future benefit. It was then necessary to take a different view or different management frame. The launch of the RIKEN Genomic Sciences Center (GSC) in 1998 may be evidence of change in Government policy for science promotion. RIKEN GSC consisted of several big

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groups, including our human genome group, and a structural biology group. Later, the Japanese government proposed the structure of biology in international projects. The Japanese government intended to organize some structure biology consortium at the international level like the HGP. I think this is one of the positive effects or influence of the human genome project or Bermuda principles. The Japanese government has shown some understanding for this kind of international cooperation or data sharing.

BCD: Regarding your participation in the human genome project and the other folks who were involved in it from Japan--how did it affect your careers, and how did your colleagues in Japan regard it?

YSakaki: After finishing the HGP, we were recognized as the leading group of large-scale genomic analysis and allowed to expand our project to other large organisms like chimpanzee, mouse and so on. That was supported as a big international project under the budget of RIKEN Genomic Sciences Center. But as a big stream, the Government shifted its direction to more medical application, such as Japanese SNP-based disease gene analysis. Later, Francis Collins proposed the Thousand Genomes Project, and I contacted the Japanese government but they were little interested in it. And I was also nominated as the director of the RIKEN GSC, in which various national and international projects were conducted. They were not necessarily so open as the HGP but still kept its spirit of international cooperation and collaboration. Is that the answer you expected?

BCD: No, I'm sorry, we were just looking over our questions that are in here trying to figure out the stuff that we haven't gone over ... so one question—this meeting happens and you go back and presumably you've got a task ahead, kind of a work order, right, a certain set of things that you've promised to do over the next year in contributing to the final sequencing. How did that work? You reached an agreement at the 1998 meeting and went back and did what you said, or how did that work? How was the Bermuda meeting used as a management tool for coordination?

YSakaki: Towards the final goal of the human genome project, we kept saying that a big sequence facility is essential. And regardless of the particular 1998 meeting I think already the government [*\*\*YSakaki: The STA, or Science and Technology Agency. \*\**] had decided to establish a new center for human genome sequencing at RIKEN. And already, our government policymakers had decided to completely contribute to the human genome project as a nation.

BCD: And what about the technical aspects of how you did the sequencing—which machines you used, what software you used, what level of accuracy you were expecting to achieve, and things like that?

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YSakaki: Let me start from 1995. Our sequencing project started from chromosome 21 under the collaboration with a German group by the BAC map-based sequencing strategy, and we discussed and agreed to give a finished, very complete sequence as the final product. But in 1998, Craig Venter started a new project to release some kind draft sequence. And we as an HGP team agreed to change the strategy, that is, to employ BAC-map based draft sequencing as a step to the final goals. It was exactly the same time when our new RIKEN center started and we were lucky to be introduced to the newest sequencers (multi-capillary sequencers). I thought—it will be very hard for us to obtain the understanding of our funders in shifting the strategy to draft sequencing in the new center, in order to follow the international policies. We thank STA but also, we very much insisted for chromosome 21 as our clear goal to give very solid data for the publications. So we just started draft sequences on one side, mainly focused to chromosome 11 and 18, with the accuracy of 99.9% or less, but on the other side we agreed with the German group to insist on very high quality (99.99% or more) for chromosome 21. So we handled two different sequencing lines to contribute to this project. And in 2000 we successfully published the chromosome 21 paper with very high quality data. But on the other side, a draft sequence, that is just some strategic change against the activities of Craig Venter. I emphasized that we did not change the final goal of the HGP. But journalists took that is some kind of struggle or fight between the private sectors and the public sectors. I kept saying to our communities, the goal of the HGP is quite different from Craig Venter's goals. I think we finally obtained people's understanding and support for the human genome project.

BCD: And did the debates that were going on about ... so this meeting took place in late February of 1998 and the Celera announcement happened about three months later.

YSakaki: Yes.

BCD: And did that affect how you went about your work and did it affect public support for or government support for your projects in Japan?

YSakaki: Of course there were various discussions we had and the industry side expressed some concern about our human genome project. The general public seemed just simply interested in watching what happened between Craig's and the international groups. The scientific community seemed completely to support us. And I should say again that it was quite important that we finish the chromosome 21 in May of 2000. That is a great landmark for Japan, showing clearly we contributed to the human genome project. So after the chromosome 21 papers the atmosphere clearly changed. It was very much favorable to us and very much supportive of us.

BCD: Yeah.

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KM: Do you think that the Bermuda principles were helpful for science in general? And also do you think that they were necessary for the completion of the human genome project?

YSakaki: Yes, of course. The Bermuda principle is quite important for the completion of the human genome project and maybe other similar huge international projects. But generally speaking, I think we need discussions about whether the Bermuda principle is good for other projects or other scientific researchers. For each project, people have their own different backgrounds, or different goals. And in many cases, they are competing with each other. Competition, although very much different from the Bermuda spirit, is one of the big driving forces for promoting science and technology. On the other hand, large-scale cooperation/collaboration for constructing some big frame or big basis for future development is also quite important for science and technology. The Bermuda principle is a good model for large-scale international projects such as the HapMap project and the Human Epigenomic project. But other small projects or other individual projects I think it is very hard for researchers to follow the Bermuda rules.

KM: Right. Do you know any of the other scientists from Japan, or administrators, who were at the earlier 1996 and 1997 meetings? I'm interested if there was some discussion in Japan among scientists about the earlier meetings, if you knew anyone who was there.

YSakaki: Okay, in the first meetings, Professor Ogasawara attended the meetings and I received some reports from him. And also probably I think Professor Hattori attended the meetings. But anyway, I think one of the Japanese people to be interviewed is Dr. Ogasawara. He was a leader of the Japanese and international *B.subtilis* genome project. Also I would like to recommend Professor Nobuyoshi Shimizu, he was also a member of the chromosome 21 consortium. Also he was a member of the international consortium for the human genome project. He did not attend the Bermuda meetings at all but I think he may be a person to be interviewed.

KM: Okay, and Professor Hattori was also there in 1996. Okay.

YSakaki: I will send you his name and his address to you. If necessary, you can contact him directly.

KM: Yes, that would be wonderful, thank you.

YSakaki: China is a latecomer to the human genome project. So by 1998, China had not yet participated in the human genome project. But later they were members, and of course in the human genome project their contribution was not so big. But after the HGP, they expanded many projects in different organisms or different aspects

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of the human genome. So I think Dr. Huanming Yang is a big person to be interviewed about these kinds of issues.

KM: Wonderful, thank you. And if you have his contact information, might you send it to me?

YSakaki: Okay, I'll give you his contact address and so on.

KM: Great. And do you have any notes or documents or anything you might have saved from the Bermuda meeting that might help us understand what happened or that might be helpful to our project?

YSakaki: Yeah, I attempted to find them but I couldn't find anything specific. I found the Abstract books from HUGO meetings, HGM '96 and '97, but nothing describing the Bermuda principles. And also I attempted to find some documents but, unfortunately, I could not find them.

BCD: And the stuff that would be of most historical significance, I think would be any interactions, documents or discussions that happened between you as a scientist and your government funding agencies in Japan, either before leading into the meeting or following up on the meeting. If there were any such documents or any such discussions that would be really, really useful to know about.

YSakaki: Okay, I'll continue the effort to find something, documents.

KM: So I'm curious. When you came back from Bermuda, or perhaps when the first scientists from the first meetings came back from Bermuda, how did you obtain exclusive permission for releasing this data for the human genome project? Because you said that there was an understanding that the human genome project was special in terms of participation in the international community. How did you obtain this special permission from your funding agency? What was that process like?

YSakaki: As I have mentioned before, the HGP was recognized as a very special project supported because of its ambitious scientific goal and also its international character. And we kept saying the acceptance of the Bermuda principle is necessary for us to play as a member of the consortium and also kept saying the necessity of a large scale sequencing facilities. Through those efforts, the funding agencies (STA and Monbusho) and also the scientific community gradually showed understanding and support to our project. The establishment of RIKEN GSC in 1998 where we were a major group was good evidence showing their understanding and support. But you can imagine we were not in the position to be able to request the funding agency to give us some written agreement about the Bermuda principles. Simply, they allowed us to release the data as a member of

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the international consortium for the success of the project under the consortium's policy or principle. We took a "non-written agreement" on mutual reliability.

KM: Right, right. Well, thank you, this has been extremely helpful. Unless [BCD] has something else to add I think we've pretty much covered all of the questions that were on our lists.

YSakaki: After I receive the written documents of this interview, then I will add a little more if necessary.

BCD: Yeah, actually, there was one thing I caught as I was going through here that we didn't go over. Who exactly invited you and how did that process work? Was it one of the ... how did you get invited to the meeting?

YSakaki: I received the invitation from Michael Morgan. I was a representative of the chromosome 21 consortium and also I was a leader of the Japanese human genome sequence project teams.

BCD: Okay, so you got your invitation directly from him. Okay.

YSakaki: Yeah, yeah, I think I received the invitation from Michael Morgan.

BCD: And were you involved with any of the meetings that happened after this that were kind of carryovers, the meetings at Fort Lauderdale or the Miami agreements?

YSakaki: Yes, I attended the Fort Lauderdale meeting. It was a little bit difficult, for me as a human genome researcher to participate in the discussions because most discussion was focused on the expansion of the Bermuda spirit to other organisms or other projects. In the year 2002 Cold Spring Harbor meeting, I proposed to release some joint declaration by the government or Prime minister and President of each country to celebrate the completion of the human genome project. And Michael Morgan prepared the final draft of this kind of declaration and we discussed it at Fort Lauderdale. Indeed when we finished the human genome project in the year 2003 this joint message was released to the public.

BCD: Cool. So is there anything that we should have asked you that we didn't think to ask you that strikes you important?

YSakaki: I will ask you, is that okay?

KM: Of course.

YSakaki: I'm wondering if this is a publication describing the Bermuda policies or is it more widely about human genome project?

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BCD: So the products of this project are going to include the archival stuff, the transcripts of the interviews and background. Those will be posted on the web.

KM: Those that are ... we are given permission to post.

BCD: The ones that are available according to the permission forms that we get back from people, we'll make those available. We intend as of right now, we don't know exactly because we're not finished with it, but we're expecting that we would write at least one history of science kind of paper that would be scholarly. And another one that would probably be more aimed at a policy audience that is interpreting how to do science and the sociology of science. And those are the main things that we are thinking about as outputs from this project. So one would be archival, the other would be scholarly publications. And we don't know, one of our collaborators is thinking that this might be complicated and interesting enough to turn it into a small book or something like that. But we haven't figured that out yet.

YSakaki: Okay. I think through the human genome project, we got a new style of policy from the Bermuda principles. But at the same time also, from my view, we learned lots about the role of the public sector and the private sector. Craig Venter is a great private sector person. He has contributed some great things to the human genome sciences. But our goal was very different from his. People or communities have not well understood the role of the public sector vs. that of the private sector, or business. From a long-term viewpoint, the public sector's contribution for establishing a solid basis of human biology and medicine is absolutely necessary for the future development of the sciences. So if through your documents this kind of discussion about the role of the public sectors and private sectors was raised, that is great.

BCD: Yeah, and we are going to try to interview Craig. That's certainly one of the themes that comes through loud and clear in these discussions about how to do science and how it works. So it's a helpful comment, thank you.

YSakaki: Okay.

BCD: Okay, thank you so much, and as I said, we will send you the transcript along with a form or what we should do with it when we get it back from you. And that will be in the next couple weeks.

YSakaki: Okay, thank you.

BCD: Thank you.

KM: Thank you so much, professor, for agreeing to talk with us.

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YSakaki: Okay, thank you too.

BCD: Thank you, bye.

END OF RECORDING

**Yoshi Sakaki—follow-up questions to original Bermuda Interview.**

**Answers received by Kathryn Maxson in email conversation with Yoshiyuki Sakaki, 17 January 2013.**

- 1) What is the current policy of the Japan Patent Office on patenting DNA-related inventions? As far as you know, is this the same policy that existed at the time of the Bermuda Rules (1996-1998)?

I am not sure about the details of the current policy on patenting DNA-related inventions, but to my knowledge, Japan, US and Europe Patent Offices had meetings many times to have a common standard on patenting DNA-related inventions. So I guess the current policy of the Japan Patent Office on patenting DNA-related inventions is different from that of Bermuda period. Today, Japan, US and EU patent office have common view on patenting DNA-related inventions, except that we lose the right to patenting if the data were released to public.

- 2) I have read that at the time of the Bermuda meetings, Japan was in the process of enacting legislation similar to the Bayh-Dole Act in the United States (1980), which would allow for more efficient technology transfer to industry of patented inventions drawing upon publicly funded research. This would have been very important in the time of the Human Genome Project in Japan because of the potential biotechnology inventions coming from publicly funded, human genomics research.

- a. Is it true that there was new intellectual property legislation at this time? If so, do you happen to know the name and year of the new law?

No, the new legislation similar to the Bayh-Dole Act started in 1999. I don't know the official name of the new Act in English, but in Japanese it means "Special Act for Reactivating Industrial Power"

- b. Would/do professors or researchers have the right to patents on publicly funded inventions, or would someone else own them (government, university, lab, industry)? If there was indeed a new patent law at the time of the Bermuda meetings, how did this situation change, if at all?

As mentioned above, the new patent act did not exist at the time of the Bermuda meetings and all the rights to patents on national funded inventions belonged to the Government.

Now, under the new law, they belong to universities and/or individual researchers and will be easily transferred to industries.

- 3) In Prof. Hattori's interview, we discussed JST's policy (during the Human Genome Project) of immediate release of unfinished sequence by researchers and a 3-month delay on the release of finished data through JST. He mentioned that this was probably not written down in a formal document. He also described how the delay was used so that JST could check and compile the data before release to DDBJ and its own database.

- a. Is this also how you understand the JST policy for sequence data at this time?

The contract with JST was done by each university, so I have not seen how the data release policy was described in the contract. However, although I don't remember exactly, the JST explained their data-release policy to us as the funding agency in a representative meeting before the start of the project in 1995 (before Bermuda meeting), and we did not think it unreasonable. JST and we paid little attention to unfinished data at that time (1995).

To my knowledge, JST did not show any official view about the immediate release of unfinished data, even after the Bermuda meeting. It seemed depend on the policy or view of each sequencing team leader. I decided as the head of our sequencing team to follow the international agreement and attempted to obtain the understanding of the STA officials to my decision. As I mentioned previously, I understood they showed understanding (not in a form of official approval) to my policy.

- b. Do you believe that patenting played a role in this delay as well? If so, how? For instance, in Europe, German and French labs were understandably concerned about immediate release of sequence data because the European Patent Office does not allow patent applications on inventions drawing from data that have already been placed in the public domain as prior art. The Bermuda Rules would thus have prevented patents drawing directly from the primary human sequence data (for instance, patents on specific genes), since this data would have been immediately released. American researchers did not have this problem due to a one-year grace period to file for patents after relevant data had been placed in the public domain. Would you mind describing the situation in Japan?

It seems partly so, since the patent condition in Japan was similar to that of Europe. But, when we started the JST project in 1995, there may have been another reason for delay of data release, that is, JST had a project to establish their own Human Genome Database independent from DDBJ and they needed time to handle the data from their partner sequencing teams before the release to public through DDBJ.

- 4) Prof. Hattori and I discussed a letter sent to Kenichi Matsubara of Osaka University in March 1998, from Francis Collins, Aristides Patrinos, and Michael Morgan. This letter was about enforcing the Bermuda Principles, but Prof. Hattori was not familiar with the letter. I am attaching it in my email to you.

- a. Did you know about this letter? If so, what are/were your reactions to it?

I did not know about the letter, and I don't know what has been done by Professor Matsubara. I would like to comment that at the time of March 1998, the Government had already decided to launch the RIKEN Genomic Sciences Center, in which a large-scale sequencing of the human genome will be carried out as an international project under my direction.

Also, as I mentioned previously, Japanese large-scale sequencing projects other than the Human Genome, such as the Rice Genome, were supported by each different Ministry or agency under their own policies, independent from the Bermuda Principles, based on their own purposes and principles. So, Professor Matsubara could do little action to non-human genome sequencing projects.

- b. Also, do you perhaps know how to get in contact with Prof. Matsubara? If possible, I would like to get in contact with him to get his recollections about the Bermuda Principles.

His e-mail address is: [matsubara@dna-chip.co.jp](mailto:matsubara@dna-chip.co.jp)

- 5) Finally, I attached two further documents to this email, along with this list of questions, Prof. Hattori's interview, and the letter to Prof. Matsubara. The two documents describe, I think, the JST program's data release procedures for human sequence data. I believe one is from 1997 and one is from 1999.

- a. Have I correctly identified these documents? If not, do you know what they are?

I have not seen those documents. I don't think those are some official ones released by JST. But the system and procedure for data collection and release described in the text meet well to my understanding at late 90s.

- b. I found these documents on the Internet by searching for genome data release policies for the HGP in Japan. They did not seem to come from a website or a report, but rather were just two free standing downloads. Do you happen to know where these documents came from? The reason is that I would like to be able to cite them properly, as they seem to be a valuable resource.

I asked Dr. Kuroda at JST and she provided me following information.

ALIS Sequencing Database for Large Scale Human Genome Project  
Genome Informatics Vol. 8 (1997) p278-279

[https://www.jstage.jst.go.jp/article/gi1990/8/0/8\\_0\\_278/\\_article](https://www.jstage.jst.go.jp/article/gi1990/8/0/8_0_278/_article)

ALIS: Data Management Systems for Human Genome Sequencing  
Genome Informatics Vol. 9 (1998) p319-320

[https://www.jstage.jst.go.jp/article/gi1990/9/0/9\\_0\\_319/\\_article](https://www.jstage.jst.go.jp/article/gi1990/9/0/9_0_319/_article)