

Protocol 1277 Informed consent statement for Oral History Interviews

(This form can be sent in advance and signed or read into the tape at the beginning of the interview.)

The interview will be recorded, and I will use the audio file to make a transcript. The transcript will be shared with you, with an opportunity to correct it. The attached form indicates options for making the final edited transcript available.

My name is Komal Kingler and I am a student at Duke University. I am in a course on the history of genomics that includes oral history. One goal is to produce a written transcript of interviews with important figures in genomics. Some of the interviews may be archived or made public through a website. The conditions for making the transcripts public (the audio tapes will not be public) are indicated in the accompanying form, and you can choose any of those options, or write in your own conditions.

I selected you as the person I would like to interview. The interview should last 30-45 minutes. Your participation in this interview is strictly voluntary, and you may withdraw at any time. You do not have to answer every question asked. The information that you choose to share publicly will be “on the record” and may be attributed to you, unless use is restricted the conditions you specify on the form.

This interview is being recorded and I may take notes during the interview. The interviews that are posted publicly will be archived as a history resource. If you prefer that the interview be used only for the course and not made public, please indicate this on the form.

One risk of this study is that you may disclose information that later could be requested for legal proceedings. Or you may say something that embarrasses you or offends someone else when they read it on a public website. The benefit of participating in this study is ensuring that your side of the story is properly portrayed in the history of genomics.

Signed: _____ Date: _____

Person interviewed: _____ Student Interviewer _____
(Print clearly) (Print clearly)

Use of archived final transcript

Members of the Duke University community, students, faculty and staff at other institutions, or members of the general public may access the digital archives. Typical research uses of interview materials include scholarly or other publications, presentations, exhibits, class projects, or websites. However there may be other uses made as well, since the materials will be available to the general public. Investigative reporters and lawyers engaged in or contemplating litigation have, for example, used the Human Genome Archive.

Your permission to post the edited, written transcript of your interview, and any related documents, to a digital archive is completely voluntary. Unless you consent to their wider use, all materials from your interview will be available only to members of the research team affiliated with this project.

The form below provides you with different options for how, when, and with whom your interview materials will be shared.

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

OR

(B) My interview materials may be reviewed, used, and quoted by students and researchers affiliated with 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

5 years from the date of this form

10 years from the date of this form

25 years from the date of this form

After my death

Other: _____ (please specify a date or condition)

Signature: Charles DeLisi Date: 12 Nov 2012

Charles DeLisi, PhD

Arthur G B Metcalf Professor

Interview with Charles DeLisi

November 13, 2012 at 11:15am

Komal Kinger: Okay so first off I wanted to say thank you for your answers and your responses over email. Since the responses were written beforehand, was there anything you felt you left out or that you wanted to add?

Dr. Charles DeLisi: No, I think I pretty much covered it.

Komal Kinger: Okay, perfect. I had some follow-up questions. When I asked about your thoughts [on email] on a large scale human genome project as opposed to a small scaled project, you mentioned that Dr. Venter was very integral to this idea. What are your thoughts on Dr. Venter being perceived as a controversial character?

Dr. DeLisi: He was important for reasons I mentioned in the Nature article. Let me backup a bit. There was a Human Genome line item in the DOE budget submission for FY 1987. It was ultimately approved by President Regan and both Houses of Congress. So the Project was launched in 1987, and we [the office and I] had originally projected that it would be completed sometime shortly after the year 2000. When NIH got involved, both the start and completion time of the Project were set back. The new completion time was 2006. That could have been a very serious mistake because the economy started to falter around 2000, accompanied by a dramatic decline in venture money. So if it hadn't been finished when it was finished, the completion date might have been after 2006 because of increased budget pressures. The fact that Craig Venter came on the scene in the early 90s accelerated competition, allowing the Project to be completed early, essentially unaffected by the economic downturn. It also showed that there was no technical or scientific reason to set the completion date to 2006 in the first place. So Craig Venter was crucial to accelerating the pace of the Project. Now, personally, what are you referring to? What criticism?

Komal Kinger: His criticism on not sharing public data when he was doing his work.

Dr. Charles DeLisi: Public data? It wasn't public.

Komal Kinger: Sorry not public data but whatever data the company was working on.

Dr. Charles DeLisi: He [Dr. Craig Venter] was probably using, which he was entitled to do, public data. I don't know to what extent he was releasing his own data; at that point I had been away from the Beltway for nearly a decade, and I wasn't following the political details closely. I personally am a very strong advocate of complete openness, and immediate data release. However, rivalries occur in science, just as in any other human endeavor—they can be helpful (as they were in accelerating the Project), and they can also be divisive when people are overly eager to claim credit. It's all part of the human condition. Venter certainly had an advantage in the sense that he had all the public data accessible to him, plus whatever data Celera was generating, and perhaps not releasing in as timely a manner as the public data was being released.

Komal Kinger: Alright. You mentioned [in the memo] that there were “very powerful historical forces” that were making this project inevitable. Could you elaborate on that?

Dr. Charles DeLisi: (laughs) That’s a good question because my statement might seem a bit mystical, but the statement has multiple threads. First we were technologically able, though that itself is not necessarily a driver. I don’t mean that in 1985 we had the technology we needed to carry out the Project, but that no new science was needed to carry it out. It was mainly a matter of planning a well organized and well funded effort to develop the robotics and computational methodologies that would allow us to scale this up in an economically viable way. At its heart it was largely a complex management and engineering problem.

But something more underlies my remark. Social as well as physical phenomena happen in a sort of cooperative way. It’s like ice turning into water or water turning into ice; there is a point (called a critical point in the physical sciences, and sometimes called a tipping point in the social sciences) where something happens, something builds up slowly and gradually and then a critical point is reached and a transition occurs. I believe that to have such a transition in the world of human interactions, requires that the minds of enough people are prepared, and that the most influential people are proponents. I believed, when I was leaving Washington toward the end of 1987, that enough people had assimilated the idea that a human genome project was politically possible, and that enough key leaders felt comfortable with that idea. Even after we got it started, when I was about to leave Washington, people were asking me if I was nervous about leaving because maybe it was going to falter. I said no, I think the project at that point had a life of its own and it had taken the next step. That doesn’t mean opposition had vanished. As late as 1990 there were still scientists trying to stop it. But I did have a general intuitive feeling—based on large numbers of people that I interacted with—in Congress, in the White House, in the Agencies, and in the community-- that the idea [for a Human Genome Project] was commonplace enough by mid to late 1987, and enough key players were behind it, that it was at a point where it was moving forward and it wasn’t going to be reversed no matter who tried.

Underlying these specifics is the more abstract notion that science is part of human nature. There is a fundamental psychological need to understand the universe. It’s a tremendous driving force; it’s very common, very pervasive, very powerful. That organic urge, coupled with being technologically capable, was no doubt a major factor in driving the initiation of the Project.

Someone said leadership is seeing a parade and getting out front. I was talking with people from many different (let’s call them) cultures—politicians, congressmen, scientists, administrators, and I also had some budget authority--that’s all there was to it; the urge was patent, I was passionate about the scientific possibilities, and so I got out in front of the parade. I’m sure a lot of other people saw the parade too and were equally passionate, but they weren’t in a position to influence the budget. I believe people like Drs. Walter Gilbert, Charles Cantor, Jim Watson Lee Hood and Robert Sinsheimer, among others, saw it coming or wanted it to happen. It was a just matter of how to convert this idea into public policy. That was difficult and challenging, and I happened to be in a position to help out with that. So I helped to shape a historical force which was there, and would likely have expressed itself in a different

way and with somewhat different timing if I were absent—but it would have expressed itself. Maybe that's more than you needed

Komal Kinger: Oh no that was perfect, thank you. What exactly about the public policy made it so difficult?

Dr. Charles DeLisi: Well there were a lot of players involved. First I had to convince the DOE, and the DOE is not a biomedical agency. It predominately supports physics, and it spends even more money on weapons. So at first glance it doesn't seem to be a natural agency for biological research, and it's certainly not a natural agency to launch a major biomedical project. It's primarily a national defense agency. The fact that the DOE had this image of being involved in the defense industry left at least some progressive biological scientists cold to the idea of DOE involvement. One prominent biologist called it a project for unemployed bomb makers, and another said it's not discussed in polite company.

There were political problems both within and outside the DOE . The image of the DOE itself was an obstacle in terms of garnering outside support. And being a physics agency was an obstacle internally—since a biological project with a 3 billion dollar price tag—even though I never intended it to be primarily a DOE project—was a source of consternation in the physics community. The internal problems we managed OK. The Assistant Secretary for Energy Research supported it, and there was no concerted effort within the Department of Energy to stop it. After it cleared DOE we had to still get approval from the Office of Management and Budget within the Administration, and we had to get approval from both the Senate and the House [of Representatives]. So that's Washington politics. I wanted to get a lot of the other agencies involved, certainly the NIH. I think I even mentioned in the memo that I wrote about the Santa Fe meeting, that the NIH should be the major player, I can't remember if I said it in those words.

So all that had to be done within Washington politics-- and then of course outside we needed to get the community on board. I felt that this itself would happen, the outside part, the community outreach. That's part of the reason we organized, Dr. David Smith and I, the Santa Fe meeting --we invited many of the leading lights in genetics and molecular biology. Once the word had spread that there was serious interest at a major federal agency, it created an optimism about political possibilities, even among those who felt DOE shouldn't be involved. In addition Walter Gilbert, Charlie Cantor and Lee Hood were all advocates, and Dr. Robert Sinsheimer, who was president of University of California at the time, was perhaps the earliest proponent. And then the Japanese, of course, were planning to do something like this, or at least they said they were, and I traveled to Japan to meet with the leading advocate (Prof Achioshi Wada), and invited him here, and talked it up. The fear of Japanese competition drew serious Congressional attention

So with all these disparate groups, all these stake holders, there was evidently a major management and coordination problem. On top of that there was concern over the position of the White House Office of Management and Budget, which had a reputation for budget slashing. I was a little surprised that Mr. Tom Palmieri, who was the boss of our budget examiner, was supportive. My feeling at that time was that they were hesitant about open-ended projects, but this project really had a very specific endpoint, a very specific goal. It was presented as an engineering project—which it was. It had general milestones

along the way so he was comfortable. In addition, it was easier to understand (technically as well as its social relevance) than particle physics. So OMB was okay with it, at a moderate budgetary level. In fact Mr. Palmieri himself gave good advice, saying something to the effect that “You’ve got to get to a point so that no matter who in Congress asks or interviews, what panels they have, everyone on that panel, every scientist on that panel has to say yes we want to do this.” He really stressed rightly the importance of outreach in the community. And that began with the Santa Fe workshop.

Komal Kinger: Okay.

Dr. Charles DeLisi: So anyway those are things we had to do [before]. The big unknown in my mind was the economy: I was fearful that if it didn’t hold, or if it faltered, Congress wasn’t going to appropriate money at the necessary levels. They were being pulled in hundreds of different directions and something large and foreign would have been very difficult to support in a substantial way. It turned out to be just the opposite of what I feared. The economy was really hot in the ‘90s and that more than anything else made it happen. I mean people can take all the credit they want to take but the fact is that if the economy weren’t good, it would have been far more difficult to have a concerted effort on this scale completed when it was. You’ll recall that the economy was uncertain when President Clinton took office, and the community was bracing for meager funding increases. Were it not for the upturn, Celera (Venter) might never have happened, the private sector might never have gotten involved. So at the time (late 80s, with a large deficit) I was concerned about the economy. But we were lucky and really fortunate. My working assumption was that the economy would be normal, but I was anxious and aware that we were planning something monumental in a stochastic environment—but you know there’s always uncertainty in everything.

Komal Kinger: So fortunately the economy was good. Going back to the budget, you mentioned that you did try and set aside some of the budget for ethical considerations. In the memo you mentioned that “this component of the project did not live up to my expectations.” So what would you have done differently to make sure it was a more prominent part of the budget?

Dr. Charles DeLisi: The ethical component?

Komal Kinger: Yes.

Dr. Charles DeLisi: Yes, we did make that a part of the budget. In May 1987 Dr. Ben Barnhardt and I visited the Institute for Ethics at Georgetown, and as a result we decided to set aside 3% for ethical studies. I left Washington three or four months after that thinking that it was in place; I didn’t think it was going to be reversed. One of the things I was referring to [in the memo] when I said I was disappointed was that my successor Dr. Robert Wood, removed the ethical component. But when Jim Watson subsequently arrived to head the NIH program he started it at NIH, and Congress insisted that DOE restart its program.

But there was an additional source of disappointment. Over the course of 15-20 years, a lot of money was spent on ethical and legal studies. From an academic point of view I think it was very well spent. I mean there were outstanding people thinking and writing about ethical issues, making various

proposals, and reminding us that there are both moral and ethical responsibilities associated with technology. So that part of it is all positive. But in terms of impacting legislation, I just didn't see it. I started looking at this again in the late 90s and I couldn't really trace any legislation. There was no notable federal legislation until 2008, and different states had their own statutes, or lack of statutes, on a whole host of civil liberty protections. I just didn't see the connection between those studies, and Federal legislation. I had a vague, poorly articulated hope for an institutionalized ethical process embedded in funding for high impact technologies, or at least a better process than we now have. In any case Federal legislation should not have taken 2 decades.

Komal Kinger: Okay, going on with that, in one of your statements you stated, "I probably should have stayed in DC a bit longer." Was there anything you would have done differently if you had stayed or do you think that would have changed the course of the Human Genome Project? If you were still there?

Dr. Charles DeLisi: Well, I don't know. There was a three year period when the DOE Office of Health and Environmental Research, which I directed, had no permanent Director. So that in itself was a problem Bob Wood was acting and as I indicated he wasn't a supporter of ethical studies, and he was not a strong advocate for genomic science. Although I don't know the specific details, I do think that under those circumstances, the DOE genomics program had to take a hit, and DOE probably didn't contribute what it could have with stronger advocacy, and with someone who could have worked with NIH.

I was fortunate to have spent 10 years as a senior investigator in the NIH intramural program before moving to DOE. I had a lot of friends at NIH, and was eager to establish a working rapport, and I believe I could have if I had remained in Washington. For example, Dr. Vince DeVita who was director of the National Cancer Institute (NCI) when I was at NCI was a supporter and eager to collaborate. He wrote me a personal note which I still have, in which he indicated his readiness to support our initiative. So if I had remained, I suspect I would have been a bit more aggressive than those who were left in charge at DOE in raising money, and somewhat more effective in talking to the public, and working with other agencies. On the other hand, I doubt that my continued presence would, in the end, have made much difference—after the idea was introduced and the economy took off, everything else was a second or third order effect

Komal Kinger: On, kind of different topic, I mentioned that the DOE was one of the agencies that wanted to retain patent rights and the Bayh-Dole Act. Could you elaborate on your answer to that question? About how did the Bay-Dole Act debates affect your own work?

Dr. Charles DeLisi: I have a favorable opinion on Bayh-Dole. I don't know about DOE, the arguments I think began after I left. Bayh-Dole allows universities to retain patent rights which I think is at the very least administratively helpful because research universities spin off numerous start-ups, and start-ups are becoming an increasingly important source of funds for universities. With respect to Myriad Genetics, without going into the legalities of it I think I expressed myself in the letter. I'm not sure that in general the public interests are best served by relying on a company to do the right thing for the public. CEOs see the stockholder as their primary responsibility. For that and other reasons, I don't think the public is best served when a company has a monopoly on an important cancer diagnostic. I'm not

making an absolutely general statement against monopolies, but I do think when it comes to health care, they should generally be discouraged.

Patenting issues are complicated. We're living in a world that as far as technology goes, differs from the world of Benjamin Franklin by a thousand of his years. We have a morass which is going to get more complicated at an increasing rate, and in my opinion it's not getting the attention that it deserves by the most senior advisory bodies. I don't know where the NAE is, where the NAS is, where the White House Office of Science and Technology Policy is. I know a lot of reports are being produced on a lot of subjects, but I don't know who studies or even reads them, and I have a hard time tracing their impact. Maybe we need a study on how much impact all these studies are having, and whether the most pressing questions are receiving the priority they should be receiving. Seriously, It seems to me the patent system needs to be looked at closely, with recommendations on whether and how to modify it, and a strategy for implementing any recommendations that might be forthcoming. Maybe that's happened already and I just don't know about it.

Komal Kinger: Very true. We are nearing the end of our interview so I have one last question for you. Could you elaborate on how the accomplishments of the Human Genome Project and your role in it has felt in regards to other accomplishments you have had in your career?

Dr. Charles DeLisi: I guess there are three components to that: what I did as a researcher, what I did as a senior executive in the Government, and what I did as a senior executive in academia. Early in my career, I worked in a number of different research areas including structural biology, membrane biophysics and immunology. Most of the impact I would say was in immunology and computational biology. The kind the gratifications in doing research are somewhat different than those that come from management. In research the best moments are those (at least for me) infrequent occasions when you really feel you've understood something that hasn't been fully understood by anyone before. It's kind of a creative experience, and personal; not quite the same as managing, or even conceiving of a large project. The role of the Human Genome Project was a role in policy as opposed to a technical role. I feel very good about what happened but I wasn't doing hands on science in genomics, so the feeling is different. I feel good about having gotten a project off the ground that spawned a scientific if not a medical revolution—which obviously dwarfs anything I did in research. What I did as Dean of the College of Engineering was a different experience than both. I presided over enormously rapid intellectual growth during my decade as head of the College, but that's another story entirely

Komal Kinger: That was perfect, thank you so much. Thank you so much for your time; it was such an honor to talk to you today. As a reminder I'll share the transcript with you before I share the final edited version, if that's all right.

Dr. Charles DeLisi: That will be great, thank you.

Komal Kinger: Thank you so much for your time, that was very insightful.

Dr. Charles DeLisi: You're welcome. Say hello to Bob [Dr. Robert Cook-Deegan] for me.

Komal Kinger: I will.

[End of Interview]