Protocol 1277 Informed consent statement for Oral History Interviews

(This form can be sent in advance and signed or read into the tape at be 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 Abhi Sanka 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: Paul Gilman Date: 11/4/12

Person interviewed: Paul Gilman (Print clearly) Student Interviewer Abhi Sanka (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.

OR

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

Signature: Paul Fulman Date: 11/14/12

(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

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Abhi Sanka (AS): My name is Abhi Sanka. Today is November 16th, 2012. It is 3 p.m. This is an interview of Mr. Paul Gilman, the former chief of staff of Senator Pete Domenici on the history of The Human Genome Project (HGP) and a couple questions on Congress and modern genomic developments. I will call Mr. Gilman in just about 30 seconds.

Phone dials. Interview begins.

Paul Gilman (PG): Paul Gilman.

AS: Hi, Mr. Gilman? How are you?

PG: Good.

AS: This is Abhi Sanka. Great to talk to you. So, I received the IRB consent form from your assistant. So, it looks like we're all set to go.

PG: Okay.

AS: So I'm just gonna get right into it. Just for clarity, this interview will focus on Senator Pete Domeinci's involvement in the HGP and will also include a few questions on Congress and modern genomic developments. Are you read to get started?

PG: Sure.

AS: Alright. So, first question: What was Senator Pete Domenici's role in the HGP, from your perspective?

PG: Haha, in many respects, perhaps the word cheerleader is a good word. Becoming an advocate of the doing of the project at a time when there was debate within the biomedical community as to whether the project was a good idea. And at a time when there was discussion about which federal agency should participate. To have a strong congressional advocate and Domenici, and what Domenici did was not just advocate as an individual but he built a group of members, especially in the Senate, who became advocates. It served to clarify the thinking of everyone who was squabbling, and your best anecdotal supporting point for that was when Jim Watson first met Pete, he introduced himself and said... you're the man who's responsible for me being here because frankly, as he made clear, because the NIH was sufficiently worried that they may not be the controlling influence in the project, they went out and recruited Watson. So, instead of just bickering, they got on with it. It's like cheerleader and then in some sense facilitator.

AS: Okay, cool. On a personal level, what do you think Senator Pete Domenici's primary motivations were in supporting the project and why do you think he thought it was an important project to advocate for?
PG: Well, I mean, obviously, he very much bought into the notion that, armed with that information, you'd usher in a new era of discovery. That was the long term outcome that, to his mind, justified considerable federal support for the activity. And the collateral benefit of that for

him was that strategies being discussed for the way the project was to be done meant that laboratories like those in his state would likely have a participatory role which he viewed as a positive thing especially in emerging areas of nondefense related activity.

AS: Alright, great, so looking back, in what way do you think Senator Pete Domenici was proud of his involvement in the HGP? I think you kind of answered this already, but if you could elaborate... looking back on his legacy.

PG: Yeah, he participated in the press briefing that followed the White House event announcing the substantial completion of the Genome in 2000. Gosh, you know I've never, I don't know.. I would imagine that somewhere, somebody has that on videotape. He made some remarks there at that time. You know, at that moment it was the completion of the work and there wasn't a great deal to be said of the realization of the possibilities that might flow from the completion of the work. It was about having gotten the work substantially done as opposed to now here are the outcomes of that work, and the accomplishments and the discoveries that we hoped to achieve. So, you know, as with everyone it was the doing of it, not the consequences of it at the time. I do think very quickly after the sort of, the picture, the picture emerged of the genome.. it became dramatically clear that the way we presume things worked was far simpler than the actual final picture would now indicate. So, is that good news or is that bad news? It's good news because there's a little bit better understanding of how things worked and bad news in that it wasn't gonna be nearly as simple as we might've hoped. So, it was in the doing of it that he was gratified. And, in that secondary objective, he had what role might non-NIH activities have played.. he would be pretty gratified that on the federal side of the project, there was a considerable amount of participation of both universities, national laboratories, the department of energy and the likes.

AS: Alright, I'm gonna shift gears a little bit. As you know, a lot of people wanted the HGP to get done. And, it began with the national -

PG: Actually, a whole lot of people didn't want it to get done too.

AS: That's true.

PG: Some of the very people I remember, the very people on the day it was announced it was substantially complete, a whole lot of people who were there applauding the moment were the very same people who had opposed the project.

AS: Wow.

PG: Because, you know, going back to the bickering at the front end, which was should we just let science take its course and let people submit their R01 grants and do their work as they see fit, or should we have a mega project. And there were a whole lot of biomedical researchers, largely university based, who said you know, let it be the way we do it now, no mega projects.

AS: Yeah, so within government, it began with the National Institute of Health and the Department of Energy vying to lead the project. As you might recall, Senator Domenici, and his

budget counterpart, Senator Chiles of Florida, sparred over which agency should lead the project. But the end result was negotiated between the two agencies themselves. So, do you think that, retrospectively, congressional involvement was a benefit or harm to this conflict?

PG: Well, you know, you, to the conflict in the narrowest sense... I've already said what I think happened there. It was congressional involvement that got them to sit down and figure out how to do it. Had there not been congressional involvement, to my mind, there's question as to whether the mega project concept would have ever gotten off the ground. The National Research Council report on how one might go about doing the project, you know, might not have had any influence, had, quite frankly, had the NIH folks thought we're just gonna ignore this discussion and we're gonna continue to do work and if we get a little more money that's terrific, we love it. But, you know, heck with these people talking about mega projects, this is just silliness. Then, as the notion of the mega project sort of gathered steam, and somebody suggested that maybe they weren't the ones to be leading mega projects, why all of the sudden mega projects wasn't such a bad idea, and if mega projects came along with mega bucks then maybe they indeed want to get in a leadership project. So, the timing of this wasn't like, "let's do a HGP and the NIH folks said where do we sign up?" They weren't so ready to sign up, and then as it became, as they became threatened, they got a little more interested, as it became clear that new dollars, they became a little more interested. And, it was all of that congressional interest that motivated people to the table. No question about it. And, Chiles, for example.. I mean, Chiles was not an active, you know, opponent of any one way or another. He expressed, you know, concern about the management of it. He and Pete would've been very happy to have the agencies work it out and get on with it. And that ultimately is what happened. But, you know, the fact that Lawton Chiles was interested, it was because he was one of the people that Pete went about educating and getting excited about the promise of it all. He did the same with Ted Kennedy.

AS: Do you think there were motives that Senator Chiles, or even Senator Domenici for that matter, motives that they had for the project that were not primarily shared by the NIH or DOE?

PG: Oh, you know, I.. the long term outcomes, the benefits of discovery.. everybody shared in that. The NIH didn't much care whether, you know, probably didn't think that any other federal agency ought to be engaged in the discussion of it other than themselves. The funny part of all that is that ultimately, the approaches represented by the two different agencies, and literally the way, the strategy for decoding the genome.. there were fundamental differences in technically how the two agencies would approach the problem, and ultimately then how the work would be done. And, that tension, came from, again, sort of, the differences between institutions of large national laboratories with... their significant assets being compute capability versus sort of the cottage industry of biomedical research that the NIH represents largely. They tried to come a little bit in the direction of the Department of Energy by creating large sequencing centers, but they never understood the role of computation in the assembly of the genome, and did rely heavily on the Department of Energy in that regard and some university help. But in the end, I would argue that the fundamental strategy of how to go about sequencing large genomes that was espoused by the Department of Energy folks, and some degree, to some very large degree by Craig Ventor, kind of won the day, and sort of set the tone for future large genome projects. That sort of, that whole aspect of okay, so there's a project, so now how do you do the project, is often not a discussed subject.

AS: That's a good segway into the next couple of questions. But before we get there, if you were to look back.. what lessons could we draw from the history of congressional involvement in the HGP. What lessons could we draw, maybe, for application today?

PG: This would sound almost radical, but sometimes they see things more clearly than the people who were immersed in the science of it. There was a whole lot of circling of wagons and protecting turf involved in the discussion of whether to do the genome project between the agencies, and the academic community and how to do it. And, the congressional involvement sort of became the.. let's get our heads out of that, and get one with doing something meaningful. You don't usually look to Congress for that kind of longer view vision but it did serve that purpose in this case. And keeping your eye on the outcomes you wanted to achieve and not the conflicts of day to day management or inter-agency memorandum served a purpose, served to focus the research bureaucracy on outcomes as opposed to you know, the day to day stuff.

AS: Do you think that the executive branch could've had a bigger role to play?

PG: Oh, you know, it did in the sense that, and I would up working in the Department of Energy for a period of time and watching the successor to Charles DeLisi participate in the interagency group that was beginning to plan and implement the project. Could, in a way, the executive branch is its agencies.. the department of energy probably being, in this case, the agency with a voice that was the most aggressive towards doing of the project. And, so again, DeLisi, in that role, really did serve to catalyze the discussion, the debate, raise it to a level that began to become of interest to members of Congress. So, the executive branch did have a role. That doesn't mean the President mentions in it in the State of the Union address, or something like that. So, it, you know, you can't, since the agencies were there, the executive branch was there.

AS: Okay, do you mind if I ask you two questions on the Bayh-Dole Act?

PG: Sure.

AS: Okay, so, you know doubt recall that as the HGP..., sorry, the HGP was getting started right as the implementation of the Bayh-Dole Act was happening. The Department of Energy was one of the agencies most resistant to the new Bayh-Dole rules. So, what was the role of your office in mediating this policy change. What did you and Denise Greenleaf have to do?

PG: Greenlaw.

AS: Greenlaw, sorry.

PG: Uh, they weren't resistant to Bayh-Dole. There were elements of Bayh-Dole that sort of, left, large pieces of their work unaffected. So, some of the defense related work. And, so it became.. little discussion within the Department of Energy, to what degree can we extend the incentives of Bayh-Dole to defense related research. And, so that was, the sort of, that part of Bayh-Dole was controversial within the Department of Energy, so the laboratories themselves engaged in defense related research saw that there were ways to handle the national security

concerns at the same time, one was trying to advance technology dissemination and development. And, there were some in the Department of Energy who were very concerned, so, we, as we developed, part of legislation that Domenici introduced, developed mechanisms for realizing the inclusion of some of the defense related research in that framework.. the Bayh-Dole framework, we had discussions with the Department of Energy policy and legal people with defense laboratory leadership with uh, hill staffers who had participated in Bayh-Dole and still had interest in the issues associated with that. Denise, and I both wound up with, Denise being the one who did most of the footwork. I was Domenici's chief of staff at that point, I had been his energy and laboratory person before that... we tried to work through proposed legislation that would, in a way that was acceptable, to the cautious among them at the DOE, bring the defense labs in that world.

AS: So, looking back, how important do you think this was to your legacy, and Senator Domenici's legacy as a Senator?

PG: Oh, well, my legacy doesn't matter. The, I think the inclusion and, really the genesis of a lot of this discussion about how to better use defense, the defense labs and the substantial investment the American taxpayer had made in them was a very good conversation to be having. And, the discussion of how can we provide the legal framework for that research to also benefit more directly the economic development that takes place in and around these technologies. That's all today a given.. today there'd be very little discussion that we have to hold these people back. I think that almost everybody would say, yeah we have to get the maximum benefit from what we do there. So, you know it started a discussion that, I think, has become kind of a consensus among people who follow these sorts of these things that there was to be a role to be played. Probably even more importantly in the institutions themselves, their minds started to be opened to these opportunities. It wasn't too long ago that I spoke to a mathematician who had been in the weapons program, and his thing was algorithims. And he had done some work in protein structure in modeling the protein structure and the prediction of protein structure that you know was quite remarkable, and ultimately he got recruited into Celera Genomics to work on some of the algorithm development for human genome assembly. He was a perfect example of a guy who started sort of pure mathematic and defense applications and ultimately life science applications. And more and more, people in that world began to think about non-defense related applications. And that probably would be, for Pete, the most gratifying thing, because it's there accomplishments you began to tally up.

AS: Alright, so, we're gonna shift gears for one last time. So, given that you've lived through all this history and also given your experience at Celera, how do you anticipate, if you could, the d such as whole or exome genome sequencing technologies, how do you interpret that culture to take shape?

PG: Oh, you know, I do think that at this point, the technology is almost irrelevant. We've gotten beyond the how you do it discussion, and any controversies there. That's all old news. It's really all about outcomes now. And so, you know, genomics is almost a word of the past because it's all the other -omics that have emerged, and all of that you know kind of even fades to, so what is it, where is it helping us. Where are we doing things differently? What discoveries have been made that have positive health outcomes. I don't think you'll find many on capitol hill

focused in on the how you get there, it's about where are they, it's sort of like you like to think about it in terms of pharmaceutical development. On the Hill, when they talk about pharmaceuticals, it's really usually a discussion do intellectual property approaches or law, how does that affect the advancement of pharmaceutical development? What about, regulation, health safety advocacy.. how does that affect it? I think the debate has moved back in that arena more than it has into the daily tools of discovery. I would imagine a number of people in the health committees and the like, because the NIH is very good about keeping them educated and keeping them up on emerging fields, they are well educated. But are there big policy issues associated with that? Are there big, sort of, you know, fits between federal agencies? One of the nice things while I was with EPA, and as they developed their take on the use of genomics, and -omics, and their relevance to their role in public health and environmental protection, the collaboration with the FDA, to some degree the National Science Foundation, the NIH, all of that was pretty easy. So, think about that relative to the institutional wars of the early genome days.

AS: That's good news.

PG: Yeah, when it became clear that EPA was moving out and doing some very interesting things on the use of genomics in predictive toxicology and the like, the Human Genome Institute was right there saying we're here to help, where do we sign up? And the signing of an interagency agreement was almost easy. So, in that sense, everybody learned a lesson from that too.

AS: Okay, that's really interesting to see. So you would say, that a lot of the attitudes, or a lot of the culture has progressed since the Human Genome Project?

PG: Yeah, they worked together and they survived. And they weren't so sure they would. And then they realized they prospered too.

AS: So do you think, what role do you think Congress should take in discussions in the media, in how.. should they articulate a lot of new developments that are coming about for society and for citizens to understand, if they should at all?

PG: Yeah, I do think that they have a responsibility in their oversight responsibility to help, to understand these directions and developments, to understand their potential consequences, I mean there's obviously areas where there continues to be interest, certainly in the ethical issues that arise and the alike. And so, there's always obviously an interest from that perspective, and when you're funding agencies you want to know what are they doing with the money, and to the extent to which they do that oversight, their sharing of the benefits of doing it, the potential outcomes of it, is both good for the agencies asking for the money and helpful because usually when Congress does these discussions they do it in a language and level that's more easily understood by the lay public. So, I do think an ongoing, active involvement by the Congress, whether that be on the appropriations side or the policy authorization side does serve the public communication and, you know, obviously the consensus that these fields of research ought to be pursued and received federal funding... you're not gonna get that enthusiasm and that consensus if you're not communicating. If the congressional involvement serves to do that alone, that's a great benefit.

AS: Alright, so last question: If you were to speak to a Congressman on the Hill, what advice would you give him on dealing with the intersection between government and genomics and science policy?

PG: Oh, you know, I think I'd probably tell him to take a day, go to a research institution. You're bound to have one in your district if you're a congressman and even if you think you have a small district, there's a pretty good chance there's either a university or a biotech company or a pharmaceutical company or a hospital that is in the field. That is doing it at some level, and you know, go and learn. And, ask them, where do they think things are headed. Where do they think things could progress. Probably, be knocked over by the enthusiasm and the excitement that people feel and you know, sort of, immerse yourself in it... take it back with you. And, have that in mind when these otherwise dry and kind of maybe somewhat boring numbers and names of projects get thrown around.

AS: Alright, great so that's all I have for you. Do you have any questions for me?

PG: Nope.

AS: Okay, so, I will transcribe this interview, and I will make sure to get you a copy of it, and you will have an opportunity to correct it.

PG: Okay.

AS: So, I thank you for your time.

PG: Sure.

AS: This has been a very enlightening interview and I've enjoyed it.

PG: Okay, and if I can be any further help let me know.

AS: Thank you so much. Have a nice day.

PG: Good luck with it.

AS: Thank you.

PG: Okay, bye-bye.

AS: Bye.

End Interview.