Phone Interview with Christine Grady

Interviewer: My first question is, what do you do?

Grady: I work at the department of bioethics at the National Institute of Health Clinic Center, and in that job I do several things: I do research on issues related to the ethics of doing research on people, so I'll do some teaching mainly on the same topic but on some other things as well, and I'm also a member of the ethics consultation service, which provides both clinical consultation for patients, families, and clinical staff in the hospital, as well as research ethics consultations for investigators and research teams … I'm also a member of the Presidential Commission for the Study of Bioethical Issues.

Interviewer: Could you explain your involvement in that commission?

Grady: Yeah. The President's Commission is one of a series of commissions that we've had in the United States to think about, deliberate in public issues about bioethics and to make recommendations to various bodies in the United States. So, the first commission that had anything to do with bioethics was the one that you said in your website, the National Bioethics Commission that was created by the 1974 Research Act. That commission did a lot of important things in terms of setting up the systems that we still operate under in respect to research. They wrote the Belmont Report; they wrote recommendations of what to do with different groups, and the current regulations are based on some of their recommendations. There was a subsequent President's Commission in the late 70s and early 80s that continued some of that work, but also took on some other things … And then there was a commission, in I guess the 90s: the National Bioethics Advisory Commission, which did a lot of research on bioethics, but also other research as well. That was followed by a President's Council on Bioethics, which immediately preceded the current commission, which is what I'm on.

Interviewer: How does your job relate to the Tuskegee study?

Grady: I would say neither my job nor my commission directly relates to the Tuskegee Study, in the instance that I had anything to do specifically about it, but since a lot of what I do in my own work is related to ethics research and some of the current systems that we have in place really emanated, emerged from the exposé of the Tuskegee study. I am certainly affected by everything that was put in place at that point in time. I also think that, you know, as a member of the President's Commission, we not only appreciate the work that previous commissions have done, but try to do equally valuable work on topics that are currently at issue. One of the topics that our commission did take up, and you might already be aware of this, but there was a historian who has spent a lot of her career studying Tuskegee, Susan Reverby, and she was visiting an archive at the University of Pittsburgh of one of the investigators that had been involved in Tuskegee, and she uncovered some files on a different study that was done in the 40s in Guatemala. This was a study also about syphilis and some other sexually transmitted diseases, but a very different study than the Tuskegee study. In fact, some say more egregious. It was a study

that started in prisons, but then moved to psychiatric facilities. Enrolled people had psychiatric illnesses, and one major part of the studies that they did in Guatemala is inject people with syphilis and also gonorrhea and chancroid, which are two other STDs as part of their experiments. They were looking for ways to prevent the development of syphilis. But the methods that they used were, first of all pretty shocking in some respects – there was no consent from anybody, they were doing these studies in pretty vulnerable people to begin with – and some of the notes from the experiments that were done show that they had low regard for any suffering or damage that they were doing to the participants in that study. So, the commission that I'm on did a historical investigation of that study in Guatemala. And then, in relation to that, the President asked for some assessment of whether or not the systems we have in place today are such that a study of that nature could no longer happen. We did a review of the kinds of protections that are in place today, some of the issues that are on the table in today's research because of the global nature of research and the different kinds of research that are being done today 40, 50, 60 years ago, and made a series of recommendations strengthening the systems, but also recognizing that the systems that have been put in place since Tuskegee are pretty solid.

Interviewer: What were the unethical components about the Tuskegee study?

Grady: I think the two most disturbing things for me: one, that at least it appears, that they say the researchers actively took steps to try to prevent some of the participants from getting treated for their syphilis once penicillin was available and known to be effective. I think that's a huge unethical aspect. And the other is that there was a lot of deception or misinformation or no information given to the participants who were encouraged to participate without knowing a real sense of what they were being asked to do.

Interviewer: What was the Tuskegee study's initial impact on research policies when it was first exposed?

Grady: Well, when it was first exposed in the 70s, that led to a series of congressional hearings, the passage of the National Research Act, and the creation of the Commission for the Protection of Biomedical and Behavioral Research. So, in many respects, it was the pivotal event in our history that led to both an examination of the scope and limitation of research, but also a whole infrastructure of regulations and systems that are designed to protect humans in research. So really, almost everything we do today built on or came about because of Tuskegee.

Interviewer: Do you think you could give examples of governmental policies that were a result from the Tuskegee study or how it plays a role in our daily lives?

Grady: Well, it led to the commission, which led to the work that the commission did, and then the development of what we call the common rule, which is a set of federal regulations that is subtitled Protection of Human Subject Research and requires any research involving human subjects, that's funded by the United States government, to be both reviewed and approved by an IRB, and also to get the informed consent of the participants in the study unless there is a very strong justification that the IRB is

approved to waive it. Those two things didn't exist before Tuskegee, but they are standard for everything; both the IRB and informed consent are pretty much the standard in research.

Interviewer: Could you discuss what an IRB is and what informed consent means?

Grady: So an IRB is a committee, it stands for Institutional Review Board. It's a committee of people, which, by regulation, has to be men and women, non-scientist and scientist, and also has to have at least one member who is not affiliated with the institution that the IRB is associated with. Every time an investigator has a proposal for research involving human subjects in any way, it gets reviewed by an IRB before it can begin. They look for a couple things: one is basically the risks that are inherent in doing the study, to the participants that are going to be in the study or are outweighed by benefits given to the participants or the value of the knowledge to be generated. That's an important task of the IRB to make that determination that requires lots of details, looking at the science, the methods, the procedures, the interventions, and everything that is proposed in the particular study, as well as the competition of the population that is to be recruited. The second thing that the IRB is supposed to look at is whether subject selection is fair. That's supposed to be who's being selected for participation and how they are being recruited or selected. The third that the IRB is supposed to look at is whether or not informed consent of the processes and information is adequate. If all of those things in the judgment of the IRB are satisfactory, they will approve the study. If not, they'll have to change it or disapprove the study. That's what IRBs do, and then, once the study begins, after it is approved by an IRB, it then gets reviewed every year. The travesty that some people have pointed out is that Tuskegee went on and on and on and nobody paid attention after a while. That's really impossible to happen, because when the IRB looks at the study every year and says, you know, what did you do this year? How many people did you enroll? What did you learn? Are there any changes in the risks or benefits of the study? It is reapproved or disapproved each year. So that's what IRBs do, and informed consent is basically the idea that people have the right to determine their own lives. As a part of that, they have the right to decide if they want to participate in research. In order to make that decision, they need to be given information on what the research is about, what kinds of things it's going to ask them to do, what the possible risks are, what the possible benefits are, what the possible alternatives are. Then, make a choice about whether or not they want to participate and to continue to have the option as they are participating, to continue to participate or stop when they want to. That's what informed consent is all about.

Interviewer: Currently, what is the awareness level of the general public regarding the Tuskegee Study?

Grady: I actually don't know if I know the answer to that question, you may know just as much as I do about that! I think that there are pockets of people: when you say Tuskegee, they're like, "Oh yes, I know." They know a little bit about it, but maybe not all the details. I think there are actually quite a few who have never heard of it and don't know anything about it. Then there are people who sort of have the facts wrong exactly what

happened there. So I don't know what the general public awareness is – I don't think it's extensive though.

Interviewer: How would you say rights and responsibilities relate to the Tuskegee study?

Grady: I don't get the sense from reading the history that there was much consideration of or attention to any rights that the Tuskegee participants might have had. I don't think that was on the minds of any of the people conducting the study. What exactly they thought about what they were doing or how they were treating people, I don't know, but I don't think rights were part of the discourse, at least it appears from the way the history has been written. I think one of the things that has arisen in response, in the regulations in response to Tuskegee, is a recognition that people have certain rights and responsibilities in regard to research. The rights are to be not harmed, to be well informed, to have protection of their wellbeing and confidentiality, and the right to withdraw. Those are all important rights that are pretty well established in the regulations of how we do research today.

Interviewer: How did you learn about the Tuskegee study?

Grady: Oh, probably in school; it is something that comes up, and since I'm in the profession of ethics, it's a topic that people talk about all the time because it's so pivotal historically.