Video Interview with Dave Samols

Interviewer: How do you think the Tuskegee study reformed bioethical policies?

Samols: Oh, it's had a major impact – it's such a highly visible and highly publicized event that it's had an impact across the United States in dealing with all human subjects. Actually the application process that you go through in order to use a human subject is very heavily bent to fairness, ethics, and proper medical practice. In general, most current experiments that involve human subjects have to involve the best clinical practice, and then on top of that, whatever you're going to study. You don't deprive people of what normally would be their benefit medically, except extraordinary circumstances for which you'd need a lot of special permission.

Interviewer: So today, if someone were to begin a research project, what kind of hoops would he or she need to go through?

Samols: So you need to do two major things. You need to write a scientific application to a review panel called the IRB, and you need to write a readable form that the patient can clearly see of what the risks and benefits are of any trial that he or she is being asked to participate in. You can't do any experiment without the patient understanding exactly what's going to happen – what the risks are, what the tests are, what the outcome is, what the goals are. We have these papers called consent forms that the patients have to voluntarily agree to – physicians are not allowed to put pressure on them – before they can be enrolled in a human study. There's a third aspect that deals with the confidentially of all the data that is generated such that it is coded and no individuals or individual names are ever involved.

Interviewer: Do you think you could discuss the rights and responsibilities involved in Tuskegee?

Samols: The main thing is that that they [the subjects] were selected without their consent – none of them knew what the process was or what the risks were or what was happening to them. We would never attempt anything like that today. Even before you get to the consent form the scientific rigor has to be evaluated by a panel of experts on the IRB committee, and they look for: Why was this patient pool selected? Are they equivalent age? Are they male or female? What is their racial and ethnic diversity? Is pregnancy permitted? Is there an age limit? You even need a scientific review if you are using tissues or samples. If you want to do tests on blood after there has been a medical procedure you need to rationalize it. Why do you need to do it? Why is there no other alternative? Why this patient pool? Do you have enough men? Do you have enough women? Are you balancing ages? Are you balancing ethnicities? All of these things have to go into any application that deals with any sort of human experimentation.

Interviewer: How have the regulations after Tuskegee influenced your own personal research?

Samols: I have had to use some human tissues and samples (surgically discarded material). Even then I had to assure the anonymity of the patient, rationalize that there was no alternative, talk about the risks of handling any human material in terms of contamination in terms of viruses, etc., how I would handle terms of disposal – you have to describe all the procedures in detail along with their rationalization. For those experiments where I've used human samples I've had to go through an extensive review process, although in my case I was going to use samples that weren't going to be used. In that case there wasn't any ethical problem besides anonymity.