E-mail Interview with Jennifer Scharf-Deering

*Please note, the interviewer sent a series of questions to Ms. Scharf-Deering. She answered them in one holistic response.

Interviewer:

- How has the Tuskegee Syphilis Study reformed bioethics policies?
- Were there human subject research regulations prior to Tuskegee?
- Today, if one were to begin a research project, what kind of hoops would he or she need to go through to achieve this (in regards to ethics regulations)?
- Our NHD contest theme is "rights and responsibilities," so what rights and responsibilities do you see being involved in the study and its legacy?

Scharf-Deering:

There are many steps ("hoops") for investigators who conduct research in academic medical centers, including Case Western Reserve University. The process of developing and carrying out a study with patients for clinical research to develop new drugs or treatments is indeed very complex. This starts with the creating a scientifically sound and important research question. If the research is not going to answer such a question, it can be considered unethical to ask for money, time, and resources, including the time of patients.

Many of the compliance regulations include meeting the requirements of funding and governmental agencies. Offices like the one where I work provide service and education to investigators throughout the process. We help with identifying sources of funding, developing budgets, looking at contracts, reviewing protocols for science and ethics, and making sure that studies, once funded, are meeting continuing benchmarks related to reporting of updates and adverse events. The review of funding contracts helps to make sure that negative results can be published. We also help make sure that if an investigator is doing work that has the potential to be patented, the interests of the investigator and institution are protected.

It can be a very long process! There are often pilot studies (small studies to see if the research hypothesis will work at all). With drugs and devices, the United States Food and Drug Administration (FDA) requires testing and research in animals before use with patients. Once the research with people begins, there are usually 4 separate stages to test for toxicity and efficacy, find the right dose, and collect data on side effects once FDA approval has been granted.

There are actually multiple committees that may look at a project, both within an institution, and at the governmental level. The committees that I work with include the review of human gene therapy and creation of transgenic species. Many of the animal

studies use mice that are made to mimic diseases that affect humans, like cancer or Alzheimer's.

It is everyone's right to have access to information; it is a shared responsibility to be educated and empowered to ask questions.