## What does the IRB do?

The Institutional Review Board (IRB) reviews all research projects that use human beings. The IRB must make sure that these human subjects are treated ethically and humanely during their participation in such research projects.

The best way to acquaint you to what an IRB does is to provide you with some of the history behind human subjects research.

For most of the 20th century, research involving human participants was not subject to any sort of review process to guarantee that the rights and welfare of the participants would be respected. Many research projects were conducted despite being unethical, hazardous, or even cruel to their participants. Some of the more notorious unethical research projects conducted during the 20th century that caused severe harm to -- or even killed -- the people who served as their subjects include:

- **The Tuskegee Syphilis Study**, which ran from 1932 to 1972 and used indigent and poorly educated Black sharecroppers in Alabama to track the natural history of untreated syphilis infections. The participants did not have any meaningful understanding of their illness and did not understand that they were participating in research that was specifically designed to track the course of the disease, rather than to cure it.
- **The Willowbrook Hepatitis Study** during the 1950s, in which retarded children institutionalized at the Willowbrook State School in New York were intentionally infected with hepatitis to track the transmission and spread of the disease.
- Atrocities committed upon the inmates of **Nazi concentration camps** during World War II by Dr. Josef Mengele and others under the guise of medical research.
- The testing of ionizing radionuclides on children and young adults without their knowledge or consent by the United States Atomic Energy Commission and Department of Energy during the Cold War.

Public outcry over these and other research projects led the federal Department of Health and Human Services to develop a set of regulations covering the use and treatment of human research participants in the United States. *The Federal Policy for the Protection of Human Subjects* [45 CFR Part 46, also referred to as *The Common Rule*] governs human subjects research supported by the Departments of Agriculture, Energy, Commerce, HUD, Justice, Defense, Education, Veterans Affairs, Transportation, and HHS, as well as NSF, NIH, NASA, EPA, AID, Social Security Administration, CIA, and the Consumer Product Safety Commission.

<u>The federal regulations at 45 CFR Part 46</u> establish a review procedure for federally funded research involving human beings. According to federal law, the rights and welfare of human subjects must be adequately protected during all phases of the research project, from inception through data collection, data analysis, writing up of results, and storage of the collected data at the project's completion.

To help New Mexico Tech fulfill its responsibilities under these federal regulations, the University has established a policy that all human subjects research conducted under its auspices must receive appropriate review and approval by a specially trained Institutional Review Board (IRB).