IRB Training

Southern Virginia University

What is the IRB?

The Institutional Review Board is an ethics committee designed to ensure the rights and welfare of individuals. While human research is necessary and critical to make major contributions to a given field, **it is not considered ethical to use individuals solely as a means to an end.**

History of Human Research

Nazi Medical War Crimes (1939-19450)

Although not the first example of harmful research on unwilling human subjects, the experiments conducted by NAzi physicians during World War II were unprecedented in their scope and the degree of harm and suffering to which human beings were subjected.

“Medical experiments” were performed on thousands of concentration camp prisoners and included deadly studies and tortures such as injecting people with gasoline and live viruses, immersing people in ice water, and forcing people to inject poisons.

In December 1946, the War Crimes Tribunal at Nuremberg indicted 20 physicians and 3 administrators for their willing participation in the systematic torture, mutilation, and killing of prisoners in experiments. The Nuremberg Military Tribunals found that the defendants had:

- Corrupted the ethics of the medical and scientific professions
- Repeatedly and deliberately violated the rights of subjects

The actions of these defendants were condemned as crimes against humanity. Sixteen of the twenty-three physicians/administrators were found guilty and imprisoned, and seven were sentenced to death.

What came from the horror of these war crimes became known as the **Nuremberg Code;** the first international code of research. It is established that in order to conduct human subject research, basic prinicples must be observed in order to satisfy moral, ethical, and legal concepts.

History of Human Research

The Syphilis Study at Tuskegee

Arguably the most notorious example in the United States of the violation of the rights and welfare of human subjects was the long-term study of black males conducted by the United States Public Health Service in Tuskegee, Alabama. This study of the natural history of untreated syphilis was initiated in the 1930s and continued until 1972.

The Syphilis Study at Tuskegee involved approximately 600 African-American men: about 400 with syphilis (cases) and about 200 without syphilis (controls). These men were recruited without informed consent and, in fact, were led to believe that some of the procedures done in the interest of research (e.g., spinal taps) were actually “special free treatment.”

By 1936, it was apparent that many more infected men than controls had developed complications, and 10 years later, reports indicated that the death rate among those with syphilis was about twice as high as it was among the controls. In the 1940s, penicillin was found to be effective in the treatment of syphilis. The Syphilis Study at Tuskegee continued, however, and the men were neither informed about nor treated with the antibiotic.

After accounts of the study first appeared in the national press, there was a major public outrage. To ensure that human rights were not violated again, the Federal Government enacted the following:

- National Research Act of 1974
- Basic HHS Policy for Protection of Human Research Subjects
- National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research

Codes and Regulations

The Belmont Report

Following the public outrage over the Syphilis Study at Tuskegee, Congress established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The National Commission was charged with identifying ethical principles to guide research involving human subjects, and developing guidelines for the conduct of ethical research involving human subjects.

In 1979, the Belmont Report was born.

The Belmont Report identifies three principles essential to the ethical conduct of research with humans:

1. Respect for persons
2. Beneficence
3. Justice

Codes and Regulations

Respect for Persons:

The principle of respect for persons can be broken down into two basic ideas:

1. Individuals should be treated as autonomous agents
2. Persons with diminished autonomy are entitled to additional protections

In other words, potential participants need to comprehend the risks and potential benefits of participating in research, and researchers should avoid influencing participation by means of explicit or implied coercion or excessive compensation.

Respect for Persons

In order to ethically require human subjects to participate in research, an informed consent process must be present so as to insure that all participants fully comprehend any psychological, emotional, or physical harm that could surface.

Subjects should: give their consent freely and voluntarily, have the decisional capacity to understand the information presented to them, and be provided complete information about the study in order to make an informed decision.

Codes and Regulations

Beneficence

Two general rules have been articulated as complementary expressions of beneficent actions:

1. Do no harm
2. Maximize possible benefits and minimize possible harms

Potential benefits need to outweigh considerations of risk and vice versa.

Codes and Regulations

Justice

Justice requires that individuals and groups be treated fairly and equitably in terms of bearing the burdens and receiving the benefits of research.

Investigators will deny approval for research in which groups are considered for inclusion simply because of their availability, their compromised position, or their vulnerability—rather than for reasons directly related to the study.

Researchers should be careful in deciding which criteria to use to ensure that harms and benefits of research are equitably distributed to individuals and populations.

Codes and Regulations

Additional Protections

Additional Protections are in place for individuals with diminished autonomy. These populations include: pregnant women, human fetuses and neonates, prisoners, and children.

Codes and Regulations

Requirements for Federal Support of Human Subjects Research

The HHS regulations require that Federal Departments and Agencies that conduct or support human subjects research must evaluate all applications for research using the following criteria:

1. Risks to the subjects
2. Adequacy of protection against these risks
3. Potential benefits of the research to the subjects and others
4. Importance of the knowledge gained or to be gained

Codes and Regulations

Engagement in Human Subjects Research

To engage in human subjects research at Southern Virginia University, a proposal must be evaluated and approved by the Institutional Review Board.

Once a project is approved, it will be subject for continuing review until the completion of the study.

Project proposals can be submitted in person to Bryce Gessell or by email to irb@svu.edu.

If you have any questions, please email irb@svu.edu.