Frequently Asked Questions about the IRB

Researchers often have questions about what the IRB is, what it does, and why their research must be reviewed by the IRB. This page contains a list of the most commonly-asked questions about this topic.

What is human subjects research?

Federal regulations define ***human subjects research*** as a systematic investigation designed to develop generalizable knowledge, and which involves the collection of data from or about living human beings.

Why does research on human subjects need a special review process?

There have been many **research projects that were conducted despite being unethical, hazardous, or even cruel**. These projects caused severe harm to -- or even killed -- the people who served as their subjects. Some of the more notorious unethical research projects include:

- The Tuskegee Syphilis Study (1932 to 1972) 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 cure it.
- The Willowbrook Hepatitis Study (1950s), in which retarded children institutionalized at the Willowbrook State School in New York were 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.

In response to these and other unethical research projects, the federal Department of Health and Human Services created a set of regulations to govern the use and treatment of human research participants. The regulations describe procedures that must be followed, but do not necessarily provide the ethical background that researchers should understand and use as a guide during their research projects.

To acquaint you with the ethics involved in human subjects research, three important documents that provide the basis for the ethical treatment of human subjects (and which were used to draft the federal regulations) are attached to this handbook.

- **The Nuremberg Code** was drafted in response to the Nuremberg War Crime Tribunals held after World War II in which Nazi officials and scientists were tried for war crimes and crimes against humanity.

- **The Belmont Report** provides a set of ethical guidelines and guiding principles that should govern Human Subjects Research. The Belmont Report established the three main ethical principles that should govern all human subjects research: Respect for Persons, Justice, and Beneficence.
- **The Declaration of Helsinki** is an official policy of the World Medical Association, that lists the basic principles to be followed in medical research and describes the ethics required of medical researchers.

Who reviews human subjects research?

Federal regulations require that research on human participants be conducted ethically and responsibly. 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 federal law, Tech 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).

New Mexico Tech's IRB is a specially trained committee of Tech researchers, administrators, and at least one non-institutional member and one non-scientist. The committee is responsible for reviewing and approving all human subjects research performed at New Mexico Tech.

I'm not sure whether my project needs IRB review. What do I do?

If you're not sure whether your project needs IRB review and approval, please consult with the IRB Administrator. Don't assume that your project doesn't need IRB approval because you're using voluntarily donated cell samples or asking people to fill out anonymous questionnaires.

Some types of research qualify for expedited review, in which the IRB Administrator and one other IRB member review and approve the project. Some other types of projects, such as anonymous questionnaires, may be exempt from mandatory IRB review, but the project must be submitted to the IRB Administrator anyway. Only the IRB Administrator is allowed to determine whether a research project is exempt from mandatory IRB review.

How do I submit my project to the IRB for review?

As Principal Investigator, you should fill out an **IRB Application Form**, attach a complete written description of your research project, sign the Application Form in the appropriate spot, and then submit the whole package to Tech's IRB Administrator. In the case of a student-run research project, the student's Research Advisor should sign the Application Form to certify that the project will be monitored.

How much lead time does the IRB need to conduct its review?

Generally, you should have your research project reviewed by the IRB at the earliest stage possible. Reviewing projects for compliance with federal regulations can be time-consuming. The IRB typically meets once per semester and as needed at other times, as determined by the IRB and/or the IRB Administrator.

New Research Projects:

New research projects that will involve human subjects can be submitted to the IRB during the proposal routing stage. As Principal Investigator, you should check the ***YES*** box in the Human Subjects Research section on the Proposal Routing Sheet. This will alert the IRB Administrator to your project, and allow him/her to tentatively determine the level of IRB review that may be required for your project. The IRB Administrator will contact you to see if you have completed an IRB Application Form for your project.

Existing research projects:

Existing projects that use human subjects and which do not have IRB approval must be reviewed and approved as soon as possible. As Principal Investigator for the project, you should contact the IRB Administrator immediately. You will need to fill out an Application Form and provide a written research protocol to allow the IRB Administrator to determine what level of review is required for the existing project. The Administrator will work with you to get the required IRB approval for your research project as quickly as possible.

Classroom demonstration projects:

Demonstrations that involve human participants must be written up and given to the IRB Administrator at least two (2) weeks before they are performed. Please note that these demonstrations CANNOT be performed until and unless they have been approved by the IRB.

How will my project be reviewed? What is the IRB looking for?

The IRB's review of human subjects research is confined solely to procedures affecting the rights and welfare of human subjects. In its review, the IRB focuses on such issues as risk to subjects, voluntary participation, informed consent, and confidentiality of the participants.

I need the federal ID numbers for Tech's IRB and Tech's Federal Wide Assurance

Contact the IRB Administrator for this information.

Where can I get assistance with IRB issues?

The IRB Administrator acts as the liaison between the University community and the IRB. The Administrator, located in the R&ED Office, can assist you in submitting your project for review, or answer any questions that you or your research participants might have regarding the federal regulations.

What happens if I perform human subjects research without IRB approval, or I fail to comply with University policy and Federal regulations regarding use of human subjects in research?

Principal Investigators and other research staff are subject to any or all of the following consequences if they perform unapproved human subjects research:

- **Mandatory destruction of all research data** collected during your project and revocation of your right to conduct research at New Mexico Tech
- **Disciplinary action**, including possible termination of your employment at New Mexico Tech
- **Civil or criminal charges** could be filed against you and/or New Mexico Tech, if a research subject has an adverse or unexpected reaction due to his/her participation in your project.
- **New Mexico Tech could have ALL of its federal funding revoked**. Some universities have experienced this after human participants experienced significant injury or died during non-IRB approved, federally-funded research projects. Federal funding could also be revoked if an audit by federal authorities reveals a pervasive culture of non-compliance with IRB rules.

IN SUMMARY:

Federal regulations that govern human subjects research must be observed by all Tech researchers. But even more important than the federal regulations are the ethical responsibilities involved in human subjects research. If you are using human subjects in your research, you have a moral obligation to do no harm to those subjects, to treat those subjects with compassion and respect, and to acknowledge those subjects' informed decisions regarding participation in your research.

It is in the best interests of all parties (New Mexico Tech, the Principal Investigator, and the research participant) to have all research projects involving human subjects approved by the IRB. Such review helps to ensure that the ethical principles of respect for persons, beneficence, and justice have been honored.