

RESEARCH ETHICS:

How to Treat People who Participate in Research



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INTRODUCTION

In Alabama from the 1930s to 1970s, researchers recruited black men to participate in a study of syphilis - a terrible disease that can cause disability and death. The researchers told the men participating that they were getting medical treatment, even though they were not. In fact, when the study began syphilis was untreatable. The researchers instead wanted to study what syphilis does to the body over time. After World War II, when a treatment - penicillin - was available for syphilis, the researchers kept the men from receiving it because they wanted to study what happened as the disease got worse. *What makes this study - the Tuskegee syphilis study - unethical? What is wrong with the way the researchers acted?*

A human exercise experiment or class survey designed by a student for a science fair seems very different from the Tuskegee syphilis study. However, is there anything about student studies that might raise ethical concerns?

Human subjects research is exactly what it sounds like. It is research that uses people as the subjects of experiments or studies. It can include giving people new drugs, doing tests on their blood, even having them take surveys. Researchers have a duty to treat the people they study ethically and respectfully. In particular, it is important to make sure that researchers do not exploit their subjects. *Exploitation is addressed further on page 9.*

Unfortunately, as the Tuskegee syphilis study shows, some people were treated horribly during research studies in the past. German and Japanese researchers, for instance, conducted terrible experiments on prisoners during World War II. Many other incidents took place before the 1970s, when some U.S. doctors experimented on hospital patients without telling them or failed to provide medicines that would have treated potentially deadly diseases. Today, there are ethical principles for research to help ensure that people who participate are not harmed and that the scandals of the past do not occur again. These principles even apply to student research projects with humans, and they are important for you to think about as you design experiments.

If people are afraid that research is unethical, nobody will participate. Without participants, it will be impossible to develop new medicines and treatments. We all benefit from the advances made possible through medical research, from more effective chemotherapy, to vaccines that protect against deadly disease, to increased knowledge about nutrition and healthy lifestyles. None of this would have been possible without the selfless contributions of millions of human research subjects.

Some people use the term "participant" and others use the term "subject" to refer to a person who participates in a research study. Both are acceptable, but here the word "subject" is used.

INTRODUCTION TO THE 7 PRINCIPLES

One way to protect the people participating in research is to consider seven principles for ethical research. They are:

1) **Social Value**

2) **Scientific Validity**

3) **Fair Subject Selection**

4) **Favorable Risk-Benefit Ratio**

5) **Independent Review**

6) **Informed Consent**

7) **Respect for Enrolled Subject**

Each principle is described below:

1. SOCIAL VALUE

To be ethical, human research studies must have **social value**. This means the study should help researchers determine how to improve people's health or well-being. Research can do this directly, by providing results that lead to better tests and treatments for disease. Research can also help indirectly, by generating information that increases understanding and guides future research. If the research doesn't help in either of these ways, it wastes money and resources. Most importantly, it is unethical to put people at risk of harm or even discomfort when neither they nor society can benefit. When researchers conduct studies that repeat what is already well known or that is based on frivolous questions, their work lacks social value. However, student science fair projects have social value even if they do not directly lead to new information about nature, the human body, or medicine. Doing experiments is essential for learning the scientific method. There is great social value in teaching and training the next generation of researchers.

Another component of social value is researchers sharing their results with other researchers and with the public. After all, if no one else is aware of the results, then the research cannot help improve people's health. Student researchers can share their research at science fairs or during class presentations.

2. SCIENTIFIC VALIDITY

It is only fair to ask people to donate their time and take risks for research that is **scientifically valid**. In other words, the research should be expected to produce useful results and increase knowledge, which is important because there is a limited amount of money and supplies for research. Research that is not scientifically valid wastes these resources. Furthermore, research only results in increased knowledge if others take the results seriously. Often researchers will not believe the results of an experiment if it does not follow the scientific method. This means that a research study must be carefully planned to answer a specific question. There should be a hypothesis to be tested, a control, and controlled variables

when appropriate. Also, experiments must be long enough and include enough subjects to make the results convincing. Researchers often say that good research is **reproducible**. This means that if other researchers did the same experiment, they would get similar results.

Sometimes a researcher hoping to get a certain result will design her research in a way that makes that result more likely. This is known as **bias**, and whether it is purposeful or accidental, it is not scientifically valid. For example, a researcher testing a new cancer drug might only choose human subjects she thinks will get better. This might make the drug look more effective than it really is. Or, a researcher testing a new drug might compare the new drug with a lower dose of an old drug. This would make the new drug look good, but it is not a useful comparison. Researchers must design their experiments to avoid conscious or unconscious bias.

No experiment is 100% valid, but researchers should design their experiments to be as good as possible.

Although researchers try to make their experiments as valid as possible, no experiment can discover the truth perfectly or completely. Researchers have to make trade-offs between getting the best data and spending too much money or taking too much time. No experiment is 100% valid, but researchers should design their experiments to be as good as possible.

3. FAIR SUBJECT SELECTION

Researchers should use **fair subject selection**; that is, they should be fair in both recruiting and deciding which people can be in the study. The goal of this practice is to be fair both to

the people who might be subjects, as well as to people who might benefit from the treatment or method being studied. All different kinds of people are needed to participate in research. Studies will eventually benefit more people if a wide range of people participate; sometimes particular medicines or treatments affect different groups of people in different ways, and it is important to discover these differences.

Further, participation in research can sometimes benefit individual subjects. So, a broad set of people should have the opportunity to participate and therefore enjoy the rewards of the research. While some people think that they have a right to participate in research because of these benefits, this is not the case. No individual has a right to participate in a particular research study. Nevertheless, whole groups of people, like those who are a certain age or race or gender, should not be excluded without a good scientific or safety reason.

On the other hand, research can be dangerous or hard for subjects. It is not fair to only use people who are easy to talk into participating, such as past cases when researchers used prisoners because they were easy to recruit. Given all of these considerations, researchers must carefully consider the research question and which people best can help answer it when deciding whom to recruit and whom to select for participation in their studies.

4. FAVORABLE RISK-BENEFIT RATIO

For research to be ethical, any risks must be balanced by the benefits to subjects, and/or the important new knowledge society will gain. This comparison is known as the **risk-benefit ratio**. The riskier the research study, the more benefit it must offer to be considered ethical. As a part of this, the risks and burdens should be as low as possible.

A research **burden** can be the time it takes people to participate or the inconvenience or discomfort it causes them. Researchers must show that they cannot answer their question

in a less risky or burdensome way. For example, if the study can be done with one tube of a person's blood, then two tubes should not be taken. In order to further improve the risk-benefit ratio, researchers should try to improve the health benefits that people get from the research. Other benefits, like getting paid, may be important to the subjects. However, such **non-medical** benefits are not considered in a study's risk-benefit ratio.

Even a research study that does not give subjects health benefits can be ethical, as long as the study is designed to potentially benefit society. For this kind of study, the risks should be low. Further, the risks should be outweighed by the benefits society gets from the study — the **social value** of the research. One example of a low-risk study that does not benefit the subjects but may benefit society is having people complete surveys or questionnaires. However, some people think that surveys, especially those that address sensitive subjects like drug use, can be risky because of the stress they might cause subjects or the potential that subjects' private information will become public. Given these worries, researchers should always be very careful to minimize risk and protect subjects, even when conducting surveys.

5. INDEPENDENT REVIEW

Researchers have a lot to consider when they design their research studies. They also believe strongly in the research they are doing. As a result, even the most careful researchers might overlook ways they could improve their research to make it more consistent with ethical principles or other requirements for research. For example, they might make the study riskier than it needs to be or might target only subjects who are easy to talk into participating. To avoid such problems, a group of people who are **not** connected to the research are required to give it an **independent review**. The group responsible for this activity is often called an **Institutional Review Board (IRB)**. If IRBs had existed in the past, many unethical studies might have been prevented.

Not only does independent review help make sure research studies fulfill all of the ethical principles, but it is also important for building society's trust in research. If people know that research has been reviewed and approved by an independent group, they will be more confident that it is ethical and that the people who participate will be treated fairly.

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For science fair projects, the independent review could include certain people, such as a teacher, a school administrator, and a person trained in psychological testing. It is especially important that IRB members are not involved in any project they review. For instance, if a parent, teacher, or researcher/mentor of a student was on the IRB, they might review their student's project more favorably. This is considered a "conflict of interest", a term discussed further on page 9.

6. INFORMED CONSENT

People who might be subjects in a research study must first be told about the details of the study. If they then agree to participate, they give **informed consent**. There are four components of informed consent. First, the subject must be **competent**. This means that he or she is mentally capable of understanding the facts about the research and making a decision based on them. Second, the researcher must give a full **disclosure**. This means that the

researcher must tell subjects what they need to know about the study, including the goals and benefits of the study and what risks subjects will face. The researcher must also tell subjects what they will have to do as part of the study and what options they have besides being in the study. Third, subjects must **understand** what the researcher tells them. A full disclosure is useless if the subject does not understand. Fourth, the subject's decision to participate must be **voluntary**, rather than the result of pressures such as **undue inducement** or **coercion**. *These terms will be addressed on page 8.*

Usually, subjects will sign an **informed consent form** to show that they have had the research explained to them and that they agree to participate. In some studies, however, there does not have to be a signed form. For example, a telephone interview is minimal risk, and it is enough for the subjects to say that they consent. Informed consent is important because in the past, researchers sometimes tricked people into participating in research. They did this by telling them they were getting medical treatment or by lying about the reason for the research.

In 1963, doctors injected live cancer cells into patients at a nursing home called the Jewish Chronic Disease Hospital. The researchers wanted to find out how fast their immune system would get rid of the cancer cells. The patients were told that this was a "skin test." Cancer is not contagious, so the patients could not have gotten cancer. Still, the study was not ethical. Even though they agreed to receive the "skin test," the patients did not give informed consent because the doctors lied to them about the purpose of the study and the tests they would get.

By law, children and teenagers under age 18 are usually not old enough to give informed consent. Also, many Alzheimer's patients, and other patients with diseases or conditions that affect the brain, are not competent to give informed consent. However, it is still important to study new medicines for children and treatments for diseases like Alzheimer's. Even if research subjects cannot give informed consent because they are not competent or are underage, it is still possible for them to

participate in research. First, a competent family member or guardian must give informed consent. Then, the subject should agree to participate, which is called **assent**. It is important to remember that for research on people who are not competent, there should be both informed consent from the guardian and assent from the subject if they are capable of giving it.

For this science fair, getting a parent's informed consent may be referred to as getting "parental permission." In this situation, think of adults as giving consent, and children and teenagers as giving assent and getting parental permission.

Elements of Informed Consent:

- Competence
- Disclosure
- Understanding
- Voluntariness

7. RESPECT FOR SUBJECTS

In order to show respect to human subjects, researchers must:

- Continue to check the well-being of each subject as the study proceeds. Researchers should remove subjects from the study if it becomes too risky or harmful.
- Keep any information about the subjects confidential.
- Allow subjects to quit the study any time they want.
- Tell subjects about any new information they may need to know. This includes new risks that the researchers learn about after the study starts and new treatments that might become available for subjects who are sick.
- Share the results of the study with the subjects, showing that they are partners in the research.

OTHER IMPORTANT CONCEPTS & ISSUES

MINIMAL RISK

Everyday life has risks. Each time somebody walks down the street, eats, drives in a car, plays basketball, or does anything else, he or she takes risks. In most cases, these risks are fairly small. For example, fewer than one in a million people die driving a car. When a study is no riskier than living everyday life, it is called **minimal risk**. Minimal risk studies do not have to benefit subjects to be ethical. However, they must at least have **social value** to make it worth using resources and taking the time of the subjects. This way, minimal risk studies still have a favorable risk-benefit ratio.

For the most part, research that high school students perform by themselves is minimal risk. Specifically, surveys and taste tests are usually examples of minimal risk research studies.

People worry that surveys can be risky if there are invasive questions, such as those found in surveys about drug use or sexuality, or if there are questions that could be traced back to the subject. However, research about surveys themselves has shown that surveys cause little stress. Likewise, taste tests are usually safe unless the subjects have food allergies or the tests involve dangerous substances.

PAYMENT & UNDUE INDUCEMENT

An **inducement** is an offer, like money. It is used to get a person to do something that he or she might otherwise not be willing to do, like a job. For the same reason, researchers sometimes offer people money to participate in research. Whether or not they should be allowed to do this is a controversial subject. Research has risks and burdens, and some worry that people will feel pressure to be subjects only because they really need money.

When an inducement is so big that it leads people to take excessive risks, it is considered an **undue inducement**. Some worry that economically disadvantaged people will feel more of this pressure. As a result, they might participate in riskier research and take on more of the research burden. This raises concerns about the ethical principle of fair subject selection. Others worry that the prospect of earning money will make people think less carefully about the risks of a research study when deciding whether to participate.

The evidence suggests that these worries may be unfounded. Many people think it is acceptable to offer people money to participate in research. Currently, researchers are allowed to pay research subjects an amount of money that is based on the research study's time and inconvenience. In these cases, independent review assesses the use of money as an inducement to help ensure that subjects are not being led to take excessive risks. After the use of money has been approved by independent review, commercials, newspaper ads, and signs offering money are commonly used to try to recruit research subjects.

An inducement does not have to be money. For example, college coaches may offer high school athletes fancy athletic shoes or the chance to go to college if they agree to play sports for the college. Or, a teacher may offer extra credit in class for students to participate in a survey.

COERCION

Coercion is a threat to make someone worse off if they do not do something. The classic case of coercion is a thief threatening: "your money or your life." In research, coercion can occur when subjects feel that there will be negative consequences if they do not participate in a study. Like undue inducement, coercion makes subjects feel pressured to

participate in research. However, coercion is different from undue inducement. Undue inducement involves an offer, while coercion involves a threat. Many college professors do research, and some ask their students to participate. If the students are worried that they will get a bad grade if they refuse, then they may feel that they are being coerced into participating in the study.

When subjects are coerced, their decisions are not voluntary. Voluntary agreement is needed for informed consent.

EXPLOITATION

Exploitation is when one person takes unfair advantage of another person. For instance, think about an older sister who talks her little brother into doing her chores. She agrees to pay him a nickel, even though she gets a dollar allowance each week for doing these chores. This is an example of exploitation. The little brother is not getting paid fairly for his work.

Exploitation of people who participate in research can sometimes occur because researchers have more power, knowledge, and control than subjects. Some worry about exploitation when researchers go to developing countries to do their research. They may not offer the people in these countries fair payment or benefits to participate in research. Others worry about exploitation when the people who participate are unable to protect themselves or stand up for what they want. Examples of such people include children, prisoners, and people who are very sick. Following the seven principles for ethical research reduces the chance that exploitation will occur.

DATA INTEGRITY

Researchers must collect, accurately record, and store the data from their experiments to have **data integrity**. Their research should be reproducible, and others should be able to look at the data from an experiment and come to the same conclusions. Researchers must not fabricate data, falsify data, or delete data for any

reason, even to make their results look better. To **fabricate** data is to make up data that is not real. To **falsify** data is to change data from what it actually is. These things are dishonest.

Another type of dishonesty is plagiarism. **Plagiarism** is when a person takes someone else's work and pretends it is hers. It is a kind of stealing and can occur when a researcher copies someone else's ideas, data, or words. Like plagiarism, it is also wrong for a person to claim that they did a research study or experiment when someone else did it for them. You may have heard about cases when parents did science fair experiments for their children. When the children present these experiments as their own work, they are being unethical.

Data integrity is part of the ethical principle of scientific validity. Without data integrity, research results are not valid. Such research wastes resources and the time of human subjects.

CONFLICT OF INTEREST

When a researcher has other goals besides answering the study question, he or she has a **conflict of interest**. For example, imagine a researcher at a college is studying whether a new drug is effective. She also owns stock in the company that makes the drug. She has a conflict of interest because there is a reasonable chance that she will make money if the drug is successful. There are also conflicts of interest that do not involve money. For example, a conflict of interest could occur if a student thinks that getting a certain result on her research project will help her earn a better grade in class.

A conflict of interest does not always mean that a study is unethical. Instead, researchers must be certain that they do not let conflicts of interest change the way they plan their experiments, understand their results, or present their results, for example, by only publishing data that supports their hypothesis. They also must **disclose** any conflicts of interest to other researchers. This way, the other researchers can watch for any bias.

It is important to think about how the seven principles for ethical research apply to specific research projects. The following are examples of how the principles might apply to students participating in a science fair.

APPLYING THE PRINCIPLES: The Stretching Study

Name: Cy N. Tist

Project: To compare dynamic and static stretching as preparation for physical exercise.

Hypothesis: Cy hypothesizes that dynamic stretching will be the best preparation. He thinks the dynamic stretching group will complete an agility exercise with a faster time.

Participants: Cy will use male and female athletes at his school. They do dynamic exercise for their sports.

Method: Cy will measure and compare subjects' average times for the agility exercise. The control group will do static stretching. The experimental group will do dynamic stretching. Cy will control for any other factors by putting subjects in the static and dynamic stretching groups randomly. This way, all the naturally fast and agile subjects will not be in the same group. Cy will include at least 25 subjects in each group, so that one or two subjects do not completely change the average time.

Results: Cy will use the average time that it takes for each group to complete the agility exercise as his results.

Principle	Application
Social Value	It is not known which type of stretching is better preparation for exercise. The answer will be useful to improve athletic practice. The information will be valuable to Cy's high school because there are many athletes and active students. There are also many P.E. classes that students take. <i>Are there any other ways in which Cy's project has social value?</i>
Scientific Validity	Cy designs his project using the scientific method. He has a clear hypothesis and a way to test it, he is controlling for extra variables, and he has a control group. He has a large enough group of subjects that his results will be convincing. He also has a clear way to measure his results: using the average time of the groups. <i>What else is important for scientific validity? What should Cy do to ensure data integrity?</i>

Principle Application

Fair Subject Selection Cy considers using his gym class as subjects. His teacher is very excited to see his results and will let him do the experiment during class. In gym class, it will be easy for him to get enough subjects. However, Cy decides to recruit athletes instead, because the study has social value primarily for athletes. *Why else might Cy decide not to use his gym class? Is it possible that some of the people in his class might feel pressured into participating? Could this be considered coercion?*

Favorable Risk/Benefit Ratio The risk of doing an agility exercise is not any greater than that of the subjects' daily lives. This makes the study minimal risk. The subjects will probably not benefit directly from being in the study, but the study's social value makes the risk-benefit ratio favorable. The subjects might benefit from learning the results of the study, but this is an example of social value. *What if the study was not minimal risk? Would Cy be able to show that there was a favorable risk/benefit ratio?*

Independent Review Cy sends his protocol and informed consent form to the people in charge of the science fair for review.

Informed Consent Cy makes an informed consent form. It states the study goal and that the subjects will not benefit. It also includes the possible risks, such as getting hurt stretching or exercising. It explains the time and activities involved in the study. It also reminds subjects that they do not have to participate. *Can Cy rely only on the form to make sure his subjects understand all of the important information about his study? How should Cy make sure that his subjects are informed and want to participate?*

Respect for Subjects Cy allows the subjects to stop if they want. His study does not take long, so no new information is discovered while it takes place. During the study, he monitors subjects to make sure that they do not look hurt or distressed. When he presents his results at the science fair, Cy does not use the names of his subjects in order to protect their privacy. Finally, he invites the subjects to the science fair to learn about his results. *If during the study Cy sees a news story saying that dynamic stretching can be dangerous, what should he do?*

APPLYING THE PRINCIPLES: The Cheating Survey

Name: Reese Urcher

Project: To find out whether and to what extent high school students cheat in school.

Hypothesis: Reese hypothesizes that none of the students in her class have cheated.

Participants: Reese will use students in her grade at school.

Method: Reese will give her participants a survey which asks them questions about cheating, and then add up the participants' answers to the survey questions. She will recruit participants during her grade's lunch period.

Results: Reese will use the number of students who admit to cheating as her results.

Principle	Application
Social Value	Reese will find out whether cheating is a problem at her high school, and her results can be used to determine whether the school should change its rules to reduce cheating. <i>What else is important for social value? Does it matter what Reese does with her results?</i>
Scientific Validity	Reese carefully words her survey to cover many different types of cheating. She takes steps to make sure the survey is anonymous. She thinks that if her subjects know the survey is confidential, they will be more likely to tell the truth in their answers. <i>How else can Reese ensure that her survey is scientifically valid? What additional steps should she take?</i>
Fair Subject Selection	Reese thought about recruiting students from her classes, but she wondered if she would be able to recruit a wide cross section of students. She decided to recruit students during her grade's lunch period so that she can get students from all classes. <i>Why else might lunch be a better place to recruit her subjects than classes, where a teacher might be watching the students fill out the survey?</i>

Principle	Application
Favorable Risk/ Benefit Ratio	Reese thinks about the fact that some students might be afraid to get in trouble for cheating. She decides to make the survey anonymous, and make the first page a cover page without any questions, so that the students will not worry that she will see their answers as they turn it in. <i>What about this survey may make it riskier than some other survey projects?</i>
Independent Review	Reese sends her protocol and informed consent form to the people in charge of the science fair for review.
Informed Consent	Reese makes an informed consent form. It states the study goal and that the subjects will not benefit. It also includes the possible risks, such as feeling uncomfortable when answering some of the survey questions about cheating. It also reminds subjects that they do not have to participate. <i>What should Reese do to make sure signing an informed consent form does not allow students' survey to be traced back to them?</i>
Respect for Subjects	Reese allows students to refuse to take the survey, or leave questions blank if they feel uncomfortable answering them. Her study does not take long, so no new information is discovered while it takes place. During the study, she monitors subjects to make sure that they do not look distressed. Reese does not attach names to the surveys, and when she presents her results at the science fair, she does not use the names of her subjects in order to protect their privacy. Finally, she invites her grade to the science fair to learn about her results. <i>What should Reese do if her friends want her to show them who has taken her survey?</i>

FURTHER READING

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INFORMATIONAL BROCHURES

The Center for Information and Study on Clinical Research Participation (CISCRP). Education Before Participation: Helping You Make an Informed Decision about Clinical Research Participation: www.ciscrp.org/information/documents/2006BrochureEnglish.pdf

The National Institutes of Health (NIH) Clinical Center Department of Bioethics:
www.bioethics.nih.gov

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