



THE BELMONT REPORT

— Plain Language Summary —

AGENCY: Department of Health, Education, and Welfare

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SUMMARY: The Belmont Report lays out the basic rules for how researchers must treat humans taking part in research. These rules are called “ethical rules.” The Belmont Report’s ethical rules try to make sure that researchers protect human research participants both physically and mentally.

Introduction

- Research has made a big impact on humans in a positive way. But some researchers have also done bad things to humans who took part in research activities. (Often, researchers call these people “participants” or “subjects.”)

- For example, during World War II some researchers used humans in experiments that harmed them badly. The Nuremberg War Crime Trials punished researchers that experimented on concentration camp prisoners.
- Many later research ethical rules were based on the Nuremberg rules. These rules are not perfect and sometimes problems occur when trying to follow them. But it is important that all researchers using humans know about these rules, so that they can protect human research participants.

A. Differences Between Practice and Research

- **Research** and **practice** can be hard to tell apart because the two can happen in a connected way. “Practice” usually is when something is done to help a person knowing it should make them better. “Research” is when someone is testing out a research question to see if a new idea is correct.
- A **research question** is a question that a researcher tries to answer through their research activity. For example, a research question could be, “Does water make grass grow better?” The researcher could then watch two patches of grass over a month. The researcher could water one patch of grass and not water the other patch and see which patch

of grass grows better. If the patch of grass that gets water grows better, then the researcher would have an answer to the question, “Does water make the grass grow better?”

B. Basic Ethical Principles for Researchers

- Sometimes researchers want to use humans in research to understand things about the human body, the human mind, or how humans act. For example, researchers could want to research if a new medication helps humans to fight a disease. Or they could want to research if a new style of teaching helps students to learn better. Sometimes researchers need to use humans as part of their research activities to answer important research questions about humans.
- When researchers use humans in their research activities, they must always follow three basic principles:
 - respect of persons,
 - beneficence, and
 - justice.
- These basic principles are the big ideas that are behind all the specific ethical rules that researchers must follow to make sure that no one takes advantage of human research participants.

1. Respect for Persons

- The “respect for persons” principle has two main parts: (1) people have a right to make their own decisions about their lives and (2) people who cannot make their own decisions about their lives need special protection.
- The first part of the “respect for persons” principle means that researchers have to respect the choices that people make. This means that when researchers do not respect a person’s ability to make their own choices, they are not valuing that person as a human being. Researchers should not stop people from carrying out their decisions or hide information that could be useful to those people to make their own decisions.
- The second part of the “respect for persons” principle means that some people cannot make their own choices and that researchers must follow special rules to protect them. Some illnesses, disabilities, or other things can limit a person’s ability to make their own choices. Researchers need to be extra careful about research that involves people with limited decision-making ability. This means that sometimes some people have to be left out of research activities so that no one can take advantage of them.

2. Beneficence

- The “beneficence” principle also has two main parts: (1) researchers have to protect humans from harm and (2) researchers have to try to make the benefits of research as big as possible for human research participants.
- The first part of the “beneficence” principle means that researchers cannot try to hurt humans they use in research activities. Sometimes one person’s pain can teach researchers important things that can help many people. But researchers have to make sure that risks of harm are as low as possible for each human participant, even if this means that researchers will learn less from their research.
- The second part of the “beneficence” principle means that researchers have to try to make the benefits of taking part in research as big as possible for the humans they use. Sometimes the people who participate in research do not themselves become more healthy or happy right away, but many other people will benefit from the research later on. This part of the “beneficence” principles means that researchers have to try their best to give clear benefits to the people who participate in the research and not just focus on helping other people later on.

3. Justice

- The “justice” principle means that researchers have to spread the good and bad aspects of their research activities among different groups of people fairly. This means that researchers have to be careful that their research activities do not take advantage of specific groups of people.
- People have different ideas about what is fair and what is not fair. For example, some people think that everyone should get an equal amount of something. Other people think that people who need more of that thing should get more of it than others who need it less. Other people think that people who try harder than others should get more. Other people think that people who are the most helpful or talented should be rewarded. It is okay for people to have different ideas about what is fair and what is not fair, but researchers still have to think about if their research activities treat human participants fairly.
- These different ideas about what is fair and what is not explains why researchers have not always treated some groups of human participants the same as others. For example, some researchers have used people of one race more than others in their research activities. Some researchers have used people who live in prisons or

institutions more than other people. Researchers took advantage of some groups of people because it was easy for them to do or because they did not think about treating those groups of people fairly. This is not allowed.

C. Rules

1. Informed Consent

- Researchers have to give human participants the chance to choose what will or will not happen to them. This is called “informed consent.” The informed consent rule has three main parts: (1) **information**, (2) **comprehension**, and (3) **voluntariness**.
- First, researchers have to give human participants enough **information** about research activities so that they can make good choices about the parts of the research activities they want to do. This includes information about the specific steps and the general goals of the research activities. It also includes information about the risks and benefits of taking part in the research activities and about participants’ right to ask questions or stop the research at any time.
- Second, researchers have to give human participants information about research activities that they can easily **comprehend** that information. (Another word for

“comprehend” is “understand”.) It is the job of researchers to make sure that human participants understand the information that they researchers give them. It is not okay for researchers only to give human participants information they do not understand. This means that for human participants who have a hard time understanding information about parts of the research, the researchers have to take extra steps to make sure they understand that information.

- Third, researchers have to make sure that human participants take part in research activities **voluntarily**. (Another way of saying “voluntarily” is “by their own choice.”) Researchers cannot push or pressure people too much to take part in research activities. Sometimes it is hard to tell when a researcher is pushing or pressuring someone too much. An example of too much pressure is if a researcher gives someone a threat that they will lose services if they do not take part in the research.

2. Assessment of Risks and Benefits

- Researchers have to be careful that the risks of taking part in research activities are not too high compared to the benefits. Some research activities are more risky than others. Researchers have to make sure that they only expose

human participants to no more risks than are needed to do the research.

- The “assessment of risks and benefits” rule has two main parts: (1) the nature and scope of the risks and benefits being weighed and (2) how researchers measure the risks and benefits.
- First, researchers have to be clear with human participants not only about if a risk or benefit is big or small but also about if a risk or benefit is likely or not. This means that researchers have to be clear that a very small risk still be very likely, or that a very big risk is not likely at all. Also, when thinking about risks and benefits, researchers have to balance carefully the possible risks to human participants with the possible benefits to society. This means that researchers can do risky research activities if they are likely to give big benefits to society.
- Second, researchers should weigh risks and benefits in a consistent way. It is hard to measure risks and benefits. But researchers’ risk and benefits assessments have to be more than just judgment calls. They have to be consistent in how they weigh risks and benefits across research projects. This means there are some red lines that researchers cannot

cross when they think about how much risk or benefit there will be for human participants:

- Researchers can never treat human participants inhumanely.
- Risks can never be more than necessary to meet the research's goal.
- Researchers have to have extra strong reasons for doing research activities that are more risky than usual.
- Researchers have to have specific reasons for using human participants from vulnerable groups.
- Risks and benefits have to be documented and shared when getting human participants' informed consent.

3. Selection of Subjects

- The “selection of subjects” rule says that researchers have to choose people to take part in research activities fairly. The people that researchers choose for research activities that have no benefits right away cannot all be from groups of people who society has treated unfairly in the past. For example, researchers cannot choose prisoners or people living in institutions to take part in research activities that are risky but do not benefit them directly, even if the research will likely benefit other parts of society. Too often,

researchers have chosen people who belong to groups
society has treated unfairly in the past. This is not allowed.