

# WHAT IS HUMAN SUBJECTS PROTECTION?

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Excerpts from material prepared by the Human Subjects Protection Administrator.

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## What is the “Human Subjects Protection” effort all about?

Human Subjects Protection is about safeguarding the welfare and protecting the rights of individuals who participate as subjects in research and non-research assessment. This gets accomplished by employing the highest standards of research ethics (core principles) and applying these in “best practice” approaches to research and non-research assessments involving human subjects. Of particular concern are issues of *vulnerability* of the subjects of one’s inquiry, protection of the subjects’ *privacy and confidentiality*, and the level of *risk* inherent in the questions being asked.

## What are the *core principles* that guide Human Subjects Protection?

Three core principles (known as “The Belmont Principles”) guide Human Subjects Protection: *respect* (acknowledging the dignity and freedom of every person); *beneficence* (maximizing the benefits of the research/non-research assessment and minimizing the harms associated with the effort); and *justice* (equitable selection and recruitment and fair treatment of subjects).

## What rules are behind Human Subjects Protection?

The formalization of a code of ethical conduct for research involving human subjects came as a result of the trials of Nazi doctors who used concentration camp inmates as research subjects. Included in the legal judgment and sentences handed down at the culmination of the trial were ten points describing required elements of conducting research with human subjects. These points came to be known as the Nuremberg Code.

## Is there a federal policy?

A number of federal regulations enacted in the 1970s and 1980s were designed to protect human research subjects. In 1979 The National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research published the “Belmont Report.” This work identified the basic ethical principles that underlie all human subject research: respect for persons, beneficence, and justice (The Belmont Principles).

The basic federal regulations (45 CFR 46) for protecting research subjects is known as the Common Rule (Dept. of Health and Human Services Regulations), adopted by numerous federal agencies and departments. The federal regulations provide three basic protections for human subjects involved in research: review by an Institutional Review Board (IRB); commitment to use informed consent; and institutional assurances that the regulations will be applied to all research.

## What are the criteria to decide whether or not research is ethical?

From the principle of respect for persons comes the need to conduct an initial (and continuing) informed consent; voluntary participation, including the opportunity to withdraw; and maintenance of the welfare of each subject. Does the consent process maximize autonomy? Does the protocol maximize autonomy? Have additional protections been put in place for vulnerable populations? Does this study maximally protect subject privacy?

From the principle of justice one needs to evaluate the social and scientific value of the research, the scientific validity of the research, and determine whether the research has a favorable risk-to-benefit ratio. Is the research design adequate? Have the risks been minimized? Have the benefits been maximized?

From the principle of justice one needs to evaluate whether there is fair subject selection, including the criteria for inclusion and exclusion and the methods of recruitment. Does recruitment for the research or assessment target the populations that will most benefit from the effort? Does it unfairly target a population? Are the inclusion/exclusion criteria fair?



### **What is the definition of a “human subject”?**

A human subject is a living individual about whom an investigator conducting research or doing a non-research assessment either: 1) obtains data through intervention or interaction with the individual; and/or 2) gains access to identifiable private information, even if obtained indirectly.

### **What if I’m working with existing data that someone else collected?**

If you are using data collected by someone else that includes identifiable private information about a living individual, it is treated no differently than if you asked that individual for the information directly. Remember, the definition of a human subject is not limited to those living individuals about whom the investigator conducting research or doing a non-research assessment obtains data through intervention or interaction directly. It may also include those living individuals about whom one gains access to identifiable private information, even if obtained indirectly.

### **What is informed consent?**

Informed consent is simply seeking permission. Subjects are to be “duly informed” of the potential risks and benefits of the research or non-research assessment, and offered the right to say “no.” Stating the purpose of the activity, identifying who is involved, clarifying issues of confidentiality, asserting the voluntary nature of one’s participation, providing contact information, and seeking permission prior to conducting the research or non-research assessment provide the basic components of a legally effective agreement to proceed. The bottom line is that the private or personal information of participants does not belong to us. Investigators are asked to honor subjects by “asking before you take.” The requirement to obtain informed consent is derived from the principle of respect for persons.

### **What needs to be included in the informed consent?**

Whether passive or active, appropriate consent notices must include: title of project, names and contact information of investigators, a statement of the purpose of the study, an outline of the procedures (as appropriate), a confidentiality statement, an assertion of the voluntary nature of participation, information about who to contact (if not the investigator), the location of the research approval (if applicable), and an informed consent statement or signature(s) (as appropriate).

### **When does active consent need to be used and when is it okay to use passive consent?**

Active consent (documentation proving that the individual agrees to participate, such as a signed agreement) should be used in cases where participants, or their parents or guardians, may reasonably express some concerns over participation, if not beforehand, perhaps during or after the research. Vulnerable populations, often, but not always, signal that it may be appropriate to seek active consent. The type of inquiry often hints strongly at whether active or passive consent (simply alerting the participant, in writing or orally, that participation is voluntary and that the act of participating provides evidence of agreement to do so) is appropriate. When highly personal, private, or other sensitive information is being sought, or generally when inquiries may provoke personal or community-level concerns about the research or assessment, it is wise to use active consent.

### **Is it always a requirement that parents or guardians provide written permission for their children to participate?**

The consent paradigm for research with children is that parents or legal guardians give permission for their children to become research subjects. Children ages 11–17 also provide *assent* (they sign too, but as a secondary feature to their parent’s or guardian’s approval). Our “best practices” philosophy would suggest that this also be the rule when conducting non-research assessments involving youth. Taking our prompt from the waivers of parental permission that are found in the Common Rule (they also apply to other elements of informed consent, regardless of age), the following may justify deviation from a strict use of the requirement for parental permission (and child assent):

- 1) the research involves no more than minimal risk to the subjects;
- 2) the waiver or alteration will not adversely affect the rights and welfare of the subjects;
- 3) the research could not practicably be carried out without the waiver or alteration; and



4) whenever appropriate, the subjects will be provided with additional pertinent information after participation.

**Can a research subject quit the study prior to its conclusion once they've agreed to begin?**

An ethical researcher must permit subjects to withdraw for whatever reason (they do not have to provide one) at any time. Any real or perceived negative consequence for not participating, or a unique benefit for participating (other than reasonable remuneration), in a study is regarded as coercing participation. The freedom to volunteer for research without coercion or undue influence from others is a central feature of autonomy that is derived from the principle of respect for persons.

**What does it mean to tell a subject that their information will "remain 'confidential'"?**

A researcher can only tell a subject that their information will remain confidential, without any qualifications, when there are no identifiers that link her/his responses to them. If one gathers the information through an interview, then one cannot make this claim. If one gathers the information on a document that has unique identifiers that link that subject with the document that will be retained, then one cannot make this claim. If one has a small or unique sample and seeks demographic or other private data that could make it clear who a particular respondent is, then one cannot make this claim. The courts have found that other interests may be more compelling than a researcher's desire to keep a respondent's information confidential, and there have been times when litigation forced a researcher to produce files that linked a particular subject with their responses. In cases when one endeavors to keep the information private but one's protocol demands that identifiers be used to track subjects, the claim of confidentiality should be modified to state that "responses will remain confidential to the extent allowed by law."

**What are "vulnerable populations"?**

Vulnerable populations include groups of people who may be more susceptible to coercion or undue influence, or may not be able to make an informed decision on their own, such as: youth under 18 years of age, institutionalized individuals, or others where participation may be considered involuntary.

**What is meant by "sensitive information"?**

The level of risk that is inherent refers to that which could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation. Sensitive personal information or private-behavior-related inquiries may also raise the level of "risk" inherent in the inquiry. The researcher would do well to consider this from the perspective of the subject, the subject's family or personal acquaintances, the subject's work, home, or community setting, etc.

**What information might be considered "sensitive"?**

The Protection of Pupil Rights Amendment (PPRA), amended by the "No Child Left Behind Act of 2001," has a provision that requires parental consent before minor students (at schools receiving any funding from the U.S. Dept. of Education) are required to participate in any survey, analysis, or evaluation that reveals information concerning: political affiliations or beliefs of the student or the student's parents; mental and psychological problems of the student or the student's family; sex behavior or attitudes; illegal, anti-social, self-incriminating, or demeaning behavior; critical appraisals of others with whom respondents have close family relationships; legally recognized privileged relationships; religious practices, affiliations, or beliefs of the student or the student's parent; or income. While we stop short of endorsing this list as always applying to our work, it offers a fair sense of the degree of sensitivity that would likely result in an investigator being expected (or required in the case of research) to carefully construct an ethically rigorous protocol, including the use of active consent.

