

# National Children's Advocacy Center

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## Statement of Principles Regarding the Use of Human Subjects

In general, the IRB's policy for protecting the rights and welfare of human subjects may be expressed in the form of three basic ethical principles: (a) respect for persons, (b) beneficence, and justice. The National Commission for the Protection of Human Subjects of Biomedical and Behavior Research identified these three principles as particularly relevant to the ethics of research involving human subjects.

### A. Respect for Persons

Respect for persons incorporates at least two basic ethical convictions: first, that persons should be treated as autonomous agents; and second, that persons with diminished autonomy are entitled to protection.

The basic ethical principle of "respect for persons" requires that people be given the opportunity to choose what shall and shall not happen to them. This opportunity is provided when legally effective informed consent is obtained. Thus, informed consent is the primary means for implementing the abstract ideal of autonomy or self-determination. The standard for the amount of information to be given to the subject is the "reasonable person" test, or how much information a reasonable person would need in order to make a decision to participate (or not to participate) in a research project. (See informed consent guidelines.)

### B. Beneficence

Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well being. Two general rules have been formulated as complementary expressions of beneficence: (a) do not harm; and (b) maximize possible benefits (including the long-term benefits that may result from improvements in knowledge) and minimize possible harms.

Every research project should be preceded by careful assessment of risks in comparison to foreseeable benefits to the subject and the importance of the knowledge to be gained. Research cannot be conducted legitimately unless the risks to subjects are outweighed by the sum of both the anticipated benefits to the subjects, if any, and the anticipated benefit to society in the form of knowledge to be gained from the research. The conduct of research must avoid unnecessary physical, psychological, or social harm and protect the subject's privacy, dignity, and feelings of personal worth. Special precautions must be exercised when the subjects may be exposed to risks greater than "minimal risks."

### C. Justice

The issue of justice concerns the use of fair procedures and outcomes in the selection of research subjects. Justice is relevant to the selection of subjects of research at two levels: the social and the individual. Individual justice would require that researchers exhibit fairness; thus, they should not offer potentially beneficial research only to some persons who are in their favor or select only “undesirable” persons for risky research.

Social justice requires that distinction be drawn between classes of subjects and the appropriateness of placing burdens of research on them. Some populations, especially institutionalized ones, are already burdened in many ways by their infirmities and environments. When research is proposed that involves risks and does not include a therapeutic component, other less burdened classes of persons should be called upon first to accept these risks of research, except where the research is directly related to the specific conditions of the class involved.

One special instance of injustice results from the involvement of vulnerable subjects. Certain groups, such as the economically disadvantaged, the very sick, and the institutionalized may continually be sought as research subjects, owing to their ready availability in settings where research is conducted. Given their dependent status and their frequently compromised capacity for free consent, they should be protected against the danger of being involved in research solely for administrative convenience, or because they are easy to manipulate as a result of their illness or socioeconomic condition.