

Guidance Document of the Protection of Human Subjects' Safety

This guidance document is designed to meet the standards as set in the *UNICEF Procedure for Ethical Standards in Research, Evaluation, Data Collection and Analysis*. It is designed to ensure effective processes and accountability for ethical oversight of these processes; to ensure the protection of, and respect for, human and child rights within all research, evaluation, and data collection processes undertaken or commissioned by UNICEF.*

The primary concern of all researchers should be subject safety. Protecting subject safety requires researchers to use all available information to identify potential risks to subjects, to establish means of minimizing those risks, and to continually monitor the ongoing research for adverse events experienced by subjects. Researchers must be prepared to stop the study if risks arise.

To assess risks and benefits, researchers need to explain and potential risks, as well as benefits, that are encountered by the research project. The term risk refers to the possibility that harm might occur. There are many kinds of risks, such as psychological, physical, legal, social, and economic hardship. The term benefit in research refers to something positive as related to health or welfare. Risks and benefits affect not only subjects, but also their families and society at large.

A. Three Basic Ethical Principles:

1. *Respect* for subjects: protecting the autonomy of all people and treating them with courtesy and respect and allowing for informed consent. Researchers must be truthful and conduct no deception.
2. *Beneficence*: The philosophy of "Do no harm" while maximizing benefits for the research project and minimizing risks to the research subjects. Subjects 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.
3. *Justice*: ensuring reasonable, non-exploitative, and well-considered procedures are administered fairly — the fair distribution of costs and benefits to potential research participants — and equally to each person an equal share

B. The basics of all human research subject protections is the fulfillment of nine functions:

1. The risks of the research are minimized;
2. The risks to subjects are reasonable in relation to anticipated benefits;
3. The selection of subjects is fair;
4. Each participant gives a voluntary and informed consent;
5. When appropriate, the research plan makes adequate provisions for monitoring the data collected to ensure the safety of subjects;
6. There are adequate provisions to protect privacy of subjects and to maintain confidentiality of data;
7. Conflicts of interest are transparent and appropriately managed;
8. Consideration is given to what additional protections, if any, are needed for vulnerable populations; and
9. Proper training in human subjects' protections is provided for research personnel.

**See: UNICEF Procedure for Ethical Standards in Research, Evaluation, Data Collection, and Analysis; Document Number: CF/PD/DRP/2015-001 Effective Date: 01 April 2015 Issued by: Director, Division of Data, Research, and Policy (DRP).*