



PONTIFICAL CATHOLIC UNIVERSITY OF PUERTO RICO  
INSTITUTIONAL REVIEW BOARD

CODE OF ETHICS OF EXPERIMENTATION ON  
HUMAN SUBJECTS

PREAMBLE

Teaching and research are two inseparable functions of an institution of higher learning. Unless supported by research, teaching would soon become outdated and empty of rigorously scientific content. It would soon lag behind, projecting a wrong image of a world in constant process of change and speaking a language both obsolete and without meaning.

Scientific research pursues the discovery of truth found at the core of the component elements of the universe. Truth, in turn, has for its primary mission to perfect the mind of man and secondarily to help him transform the surrounding world so that he may lead a life of comfort, in freedom and with the dignity the Creator wanted him to possess.

Scientific research often takes place upon human subjects. When such is the case, it is necessary to protect man against unjustifiable hazards as regards his life, his psychic and physical integrity, his personal freedom and dignity. This is precisely the principle underlying this code of Ethics that researchers should observe in carrying out any specific project of experimentation with human subjects.

As the experimental projects we have in mind will be conducted at a Catholic University, the present Code of Ethics must necessarily conform to the natural law and the revealed law of God. This is so as both laws are ordained to safeguard man's moral and spiritual values far transcending the material universe.

## Title One

### Experimentation and the Sanctity of Human Life

**Art. 1.** Human life is sacred and inviolable by virtue of it being incomparably superior to any other temporal or material values.

**Art. 2.** Any experiment leading to the direct destruction of human life is both unlawful and immoral.

**Art. 3.** Human nature is inherently gifted with values not derived from society, and under no circumstances would it be permissible to sacrifice one single human life in the interest of the common good of the former.

**Art. 4.** Every form of experimentation that would deliberately and directly result in a physical, psychic, mental or emotional injury of the human person is immoral.

**Art. 5.** Scientific experiments that pose a serious risk to the life or health of the human individual are also unlawful and immoral, unless they are performed for a legitimate and proportionate cause

## Title Two

### Human Experimentation for the Benefit of Society

**Art. 1.** Man is an integral part of society, and is morally bound to strive after the promotion of its greater possible good on the physical, cultural and moral level.

**Art. 2.** In the interest of society, it is lawful to conduct experiments, within the framework of reasonable conditions, even though the former are accompanied by moderate risks to the life, health or physical integrity of the subject of experimentation.

**Art. 3.** The good of society, to be such, must respond to man's nature and promote his moral and spiritual growth, and be made accessible to the largest possible number of citizens.

**Art. 4.** The experiments with human subjects for the benefit of society that pose some specific risks to their life, health, physical, psychic integrity or social status will be lawful to the extent and within the limits that the expected benefits exceed the foreseen dangers.

**Art. 5.** The ration between benefits and risks shall be determined by qualified professionals not related to the investigator and guided by valid scientific standards and a high sense of honesty.

**Art. 6.** Only those individuals are to be allowed to participate in an experiment who, after being duly informed of the nature and conditions of the experiment, will freely offer to do so.

### Title Three

#### Human Experimentation for the Promotion of Science

**Art. 1.** Both science and technology in agreement with the dictates of ethics and morals are good in themselves, and their promotion through experiments with human subjects is legitimate and praiseworthy.

**Art. 2.** No one is allowed to submit to experimentation without any restrictions or with a total disregard of the dictates of the moral law, just for the sake of science and technological progress.

**Art. 3.** The experimentation conducted for an exclusively scientific purpose may be allowed, when the foreseeable risks to the subject are minimal, or fall within reasonable limits in the physical, psychic, moral or social order.

**Art. 4.** It runs contrary to ethics and the moral law to offer or demand a strictly called monetary compensation in exchange for any person's passive cooperation in a scientific experiment. The opposite would be equivalent to setting a material prize to the human person, which evidently amounts to an unacceptable transposition of values. A compensation, however, may be offered as long as it will not constitute an unjust incentive.

### Title Four

#### Possible Subjects of Experimentation

**Art. 1.** Only those persons of legal age and in full use of their mental faculties may freely choose to be subjects of an experimentation.

**Art. 2.** Those individual who are either married or under religious vows, may not submit themselves to an experimentation without due authorization from the respective spouse or religious superior, unless the experiment is undertaken for therapeutic reasons.

**Art. 3.** Those persons whose freedom of action is totally or partially restricted, as in the case of those confined to prison or on Government service, may not be compelled to undergo any scientific experiment against their will, especially when it is accompanied by serious risks.

**Art. 4.** Patients in their terminal stages may not be used as subjects of an experiment that would likely lead directly to their death, even assuming their tacit or expressed consent.

**Art. 5.** Psychiatric patients, the mentally retarded, and minors do not qualify for any experimentation without the previous informed consent of their parents, tutors or legal representatives.

**Art. 6.** A pregnant woman may not lawfully submit to any scientific experiment that would pose a serious threat to the life of the fetus. Should the risk arise indirectly, the experimentation would be lawful and morally permissible to the extent that the expected benefits in behalf of the mother or of the fetus itself are proportionate to the foreseeable risks.

**Art. 7.** It is unlawful and immoral to conduct any type of experiment in aborted fetuses still alive, except when the experiment is intended to save their lives and assist them in their subsequent normal growth.

**Art. 8.** Experimentation with dead human bodies is permitted on condition that due respect to the human remains be given, and the just laws of the State regarding the matter be observed.

**Art. 9.** No one may be forced to assist in an experimentation or research project with human subjects against the **dictates** of his own conscience.

## Title Five

### Informed Consent

**Art. 1.** In order that an experiment with human subjects may be ethically and morally permissible, it is mandatory to secure first the informed consent of the subject of the experimentation or his legal representative, given orally or in writing.

**Art. 2.** The information to be provided so that the consent may be informed includes the following:

- a. explaining to the subject, his parents, tutor or legal representative, the purpose and the techniques of the experiment, its different stages, its duration, and other possible alternatives;
- b. describing the participation expected of the subject, possible dangers, anticipated benefits, security measures to be applied to deal with the risks that might unexpectedly arise;
- c. informing the subject of the tests previously conducted in animals and the results achieved;

- d. acquainting him with the training and moral sense of responsibility of the scientists carrying out the experiment;
- e. assuring the subject of his freedom to interrupt the experiment at any of its stages for a reasonable cause without incurring in any civil or criminal responsibility.

**Art. 3.** Any information obtained in the course of the experiment shall be held strictly confidential, and no disclosure of same will be permitted without the consent of the subject.

**Art. 4.** The IRB will inform the Administration of the University of the damages or injuries sustained by the subject as a result of failure of the investigator to comply with the provisions of the Code of Ethics and of the CFR, or serious negligence or error committed in the process of the experiment.

## Title Six

### Property Rights of the Results the Experiment

**Single article.** The property rights of the results of the experimentation for publication, or other possible uses, will be determined according to the existing laws of the State in relation to scientific and cultural activities.