Drafting Rules for the Informed Consent, recommended by the CIOMS

I. INDIVIDUAL INFORMED CONSENT

In every biomedical research with human subjects, the presumed subject must grant informed consent to the researcher, or, in case of the person lacking capacity to give his/her informed consent, the duly authorized consent through a proxy.

II. INFORMED CONSENT

1. General rule, Informed Consent

A procedure will only be possible after the person involved has given his/her free and unequivocal consent.

Such person shall previously receive appropriate information about the purpose and the nature of the study, as well as its risks and consequences.

In any given moment, the person involved may withdraw his/her consent.

2. Basic information for the presumed subjects of research

Before requesting a person's consent to take part in a research, the researcher must provide the following information, in a comprehensible language:

A. The individual nature of the invitation to participate as subject of the research, as well as the research objectives and methods;

B. The foreseen duration of the subject's participation;

C. The benefits, for the subject or for others that should be reasonably expected as a result of the research;

D. Any foreseeable risk or discomfort for the subject, resulting from his/her involvement in the research;

E. Any alternative procedure or treatment that could be as beneficial for the subject as the procedure or treatment that is being tested;

F. The limit up to which the confidential nature of the records in which the subject's nature is indicated;

G. the scope of the obligation of the researcher, in case of having such, to provide medical services to the subject;

H. That treatment will be administered for free for the injuries resulting from the research;

I. That the subject, his/her family or relatives that depend on him/her are indemnified in case of disability or death resulting from such injuries, outcome of the research, and

J. That the person has full freedom of refusing to participate and that he/she will have full freedom to withdraw from the research at any given moment without entailing a sanction or the loss of benefits that he/she had before taking part in the investigation.

3. Incentives to participate

Subjects will get paid for the inconveniences they go through and the time they lose, the expenses that they make related to their involvement in the research will be reimbursed; free health care will also be provided to them. However, payments shall not be that high or medical services so wide that induce the presumed subjects to consent their involvement in a research against to what their sound judgment dictates ("undue incentive"). Every payment, reimbursement and medical service that will be provided to the research subjects must be authorized by an ethical assessment commission.

4. Research with minors

Before starting researches with minors, the researcher must make sure that:

A. The minors do not participate in researches that could be carried out equally well with adults;

B. The aim of the research is to obtain knowledge applicable to the needs of the minors' health;

C. The parents or the guardian of each minor has granted his/her written consent;

D. The consent of each minor has been granted at the extent of his/her capacity;

E. The refusal of the minor to participate in the research is respected unless that, in accordance with the corresponding protocol, the minor must receive treatment because there is no other medically acceptable alternative;

F. In case of procedures that do not prove to be a benefit for the minor, it should be assured that the risk is low and proportioned regarding the significance of the knowledge that will be acquired, and

G. the procedures made with the aim of providing a therapeutic benefit will probably result to be as beneficial for the minor – subject as any other available alternative.

5. Research with people that suffer mental illnesses or behavioral disorders

Before starting research with people that given their mental diseases or behavioral disorders are incapable of granting a sufficiently informed consent, the researcher must verify that:

A. Such people are not subject of researches that can be carried out equally well with people that are in full possession of their senses;

B. The purpose of the research is to obtain knowledge applicable to the needs of people with mental illnesses or behavioral disorders;

C. The refusal of the subject to take part in the research is respected unless that, in accordance with the corresponding protocol, the subject must receive treatment because there is no other medically acceptable alternative;

D. The informed consent of the guardian or another duly authorized person in the case of disabled subjects must be obtained;

E. The level of risk assigned to the procedures whose purpose is not to benefit the subject individually is low and proportionated regarding the significance of the knowledge that will be acquired, and

F. That it is probable that the procedures are made with the purpose of producing a therapeutic benefit at least as beneficial as any other option.

6. Research with prisoners

The prisoners with serious diseases or in risk of contracting them shall not be deprived from medicines, vaccines or other experimental agents with therapeutic effects or promising prophylactics.

7. Research with subjects of communities in economic or educational disadvantage

Before starting research on subjects of communities in economic or educational disadvantage, both in developed or developing countries, the researcher must verify that:

A. People in economic or educational disadvantages don not participate regularly on researches that can be carried out equally well in developed communities;

B. The research responds to the health needs and the priorities of the communities where it is carried out;

C. The ethical imperative of the consent of each subject to be informed, and

D. The research project has been tested and approved by an ethical assessment commission that consists of consultants and people that are completely familiarized with the customs and traditions of the community.

8. Informed consent for epidemiological studies

In several types of epidemiological researches, personal informed consent is unviable or not recommendable. In such cases, the ethical assessment commission must determine if it is ethically acceptable to proceed without an individual informed consent, and if the researcher's plans of safeguarding the safety of subjects, respecting their right for intimacy and maintaining the confidential nature of data are appropriate.

II. SELECTION OF SUBJECTS FOR RESEARCH

9. Equitable distribution of risks and benefits

People or communities who will be invited to participate in subject quality researches must be selected in such way that the risks and benefits of the research are distributed equitably. A justification is required to invite vulnerable people, and, in case of being selected, the mechanisms to protect their rights and their wellbeing must be applied in a particularly strict manner.

10. Selection of pregnant women or women that breastfeed as subjects of research

Under no circumstances pregnant breastfeeding women should be subjects of non-clinical research, unless such research does not pose more than a minimum risk for the fetus or the infant and its purpose should be to acquire more knowledge on pregnancy and breastfeeding. As a general rule, pregnant or breastfeeding women should not be subject of clinical essays, except for those whose purpose is to protect or improve the health of pregnant or breastfeeding women or fetuses or infants, and for those studies in which non pregnant or breastfeeding women do not constitute appropriate subjects.

III. CONFIDENTIAL NATURE OF DATA

11. Protection of the confidential nature of data

The researcher must establish secure safeguards of the confidential nature of data that are obtained along the course of the research. The subjects must be informed about the limitations of the researchers' capacity to protect the confidential nature of data and the consequences that follow in case of infringement.

IV. COMPENSATIONS TO SUBJECTS OF RESEARCH BY ACCIDENTAL INJURIES

12. Right of subjects to indemnity. Research subjects that suffer physical injuries as consequence of their involvement have a right to receive financial or other type of aid that indemnifies them for any temporary or permanent deficiency or disability. In case of death, the relatives dependent of the subject have the right to be indemnified. The right to indemnity is inalienable.

ASSESSMENT PROCEDURES

13. Formation and roles of the ethical assessment commissions

Every research project with human subjects must be submitted to an independent ethical and scientific assessment commission, or to more than one, for its valuation and approval. The researcher shall not initiate the research until the Project is approved.

VI. RESEARCH WITH EXTERNAL SPONSORS

14. Obligations of the sponsor organization and the host country

Research with external sponsors entail two ethical obligations:

A. The external sponsor organization must submit the research protocol to an ethical and scientific assessment in compliance with the regulations of the country of said organization, and the ethical rules that apply cannot be less strict than the ones that will be applied if the research was carried out in that country.

B. After the scientific and ethical approval in the country of the sponsor organization, the corresponding authorities of the host country, among them a national or local commission of ethical assessment or equivalent organization shall make sure that the research project adheres to the local ethical regulations.

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