

ETHICAL GUIDELINES FOR FAPESP-SPONSORED RESEARCH ON HUMAN POPULATIONS ⁽¹⁾

Group on Bioethics and Population Research (2)

The guidelines were developed for the Fundação de Amparo à Pesquisa do Estado de São Paulo (FAPESP) by a group of professors of distinct Universities in São Paulo city. The guidelines were inspired by the Brazilian Society of Tropical Medicine Code of Community Health Rights ¹; the Resolution 01/88, Ministry of Health National Health Council ³; the Federal Medical Council Medical Ethical Code ²; and the CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects ⁴.

The FAPESP-guidelines are intended for use of biomedical and human sciences (*latu sensu*) researchers applying for grants in projects involving human subjects. The ethical aspects of the project will be first appraised by the referee(s) and subsequently by the coordinators of the area to which the project belongs (Health or Human Sciences); the third instance to appraise it will be a review board specifically designated by the agency that will have the purpose to eliminate any ethical conflicts remaining in the project.

It is intended for the FAPESP-guidelines to be reviewed within 3 to 4 years.

ETHICAL GUIDELINES

All research on human populations will include a statement by the principal investigator declaring the project was written following these guidelines.

The guidelines are meant for research carried out on human populations. On the planning stage, the principles of human rights such as autonomy, beneficence, non-maleficence and justice ought to be considered as

well as the ones concerning human groups. Specific guidelines may not be applicable for non-experimental research in the area of Human Sciences.

PREMISES

- 1 - The research subject is free whether to participate in a research or not and the decision must be taken under no constraints of any nature;
- 2 - Communities are also free to decide whether to take part in a research or not;
- 3 - Care taken on ensuring ethics principles to be obeyed should bear a direct relationship to the vulnerability of a community;
- 4 - Probability risks are part of all research, ethically-ruled research not excluded. An ethically correct research project must estimate and evaluate such risks as well as the benefits that will result from the research;
- 5 - Research carried out in communities should be translated into benefits that will continue once the research is finished; the more vulnerable the community the more long-lasting such benefits ought to be. The burden of a research should not fall on a vulnerable community;
- 6 - If research is carried out in communities the project should contemplate whether the needs of each member in that community are being met. The differences among members must be estimated as well, in order to be respected.

RECOMMENDATIONS

- 7 - The research subject as well as the communities

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- must be considered totally free to remain or withdraw from it at any given moment without being submitted to any constraints;
- 8 - It is of utmost importance that consent be freely given and the traditions and culture of individuals or communities be respected while in the process of obtaining consent, in the project plan and during the length of the research;
 - 9 - Under no circumstances the decision of the subject or the community may be disobeyed by the researcher under the excuse that he/she knows what is better for the community or the subject;
 - 10 - Research should not be conducted on children, prisoners, military personnel, mentally disturbed or mentally retarded persons or persons under any other condition leading to reduced autonomy if it is possible to do it on autonomous individuals with the same foreseeable results;
 - 11 - Research on fertile women involving diagnostic or therapeutic procedures can only be carried out if one is assured the woman fully understands the purpose of the research and after she has been advised to avoid pregnancy in the period;
 - 12 - The possible benefits of a research as well as eventual damage resulting from it ought to be foreseen and estimated in the research project;
 - 13 - No damage from any research ought to outweigh the benefits it may bring to an individual or a community;
 - 14 - No research should be conducted at a vulnerable community if it can be conducted at a community having stronger material and social resources;
 - 15 - Payment of a research subject should not exceed the limits of reimbursement for expenses related to transportation, food, etc. The amount given to each subject should be established for each case.
- 17 - For the community or the individual to be able to decide freely whether to participate or not as research subject clear and understandable information must be provided on the nature, objectives, foreseeable results and eventual risks of the proposed research. The help of an anthropologist may be necessary in community work in order to ensure a better understanding scope of the research by each member of the community. Of great value in such cases is the help of representatives of the community who may help to establish communication between the researcher and the community although he/she is not competent to give consent for others. For research conducted in communities consent of autonomous people is always given individually.
- 18 - For medical and biomedical research informed consent will always be in writing, as recommended by the National Health Council Resolution (01/88).
 - 19 - For individuals with reduced autonomy informed consent will be given by a parent or a guardian. Whenever possible the researcher will try to get the subject's agreement also.
 - 20 - When children of a certain age and understanding and adolescents will be the subjects of a research his/hers opinion on whether to take part or not on it should be asked although consent, from a legal point of view, will be given by a parent or guardian.

REFERENCES

- 1 - Code of Community Health Rights. *Rev. Inst. Med. trop. S. Paulo*, 28: 278, 1986.
- 2 - BRASIL. CONSELHO FEDERAL DE MEDICINA - Código de ética médica. Resolução CFM nº 1246/88. Rio de Janeiro, Idéia & Produções, 1988. 63p.
- 3 - BRASIL. CONSELHO NACIONAL DE SAÚDE - Resolução nº 01/88, Capítulo I-XV. *Diário Oficial da União*, Brasília, 14 jun. 1988. p. 10.713-10.718. (Republicado no *Diário Oficial da União*, Brasília, nº 4, 05 jan. 1989).

PROCEDURES

- 16 - Biomedical research will follow the rules esta-