

## **Purpose and Guiding Principles of the Maine Bureau of Health Institutional Review Board<sup>1</sup>**

### *Purpose*

The Maine Bureau of Health (BOH) is committed to preventing disease and injury and improving health for all Mainers. BOH is also committed to the protection of human subjects participating in public health research and assuring that the rights and welfare of human participants in research are protected in the conduct of all public health activities. BOH follows The Code of Federal Regulations, Title 45 CRF Part 46, The Public Health Service Act as amended by the Health Research Extension Act of 1985, Public Law 99-158 which sets forth regulations for the protection of human subjects.

### *Guiding Principles*

The general conduct of biomedical studies is guided by statements of internationally recognized principles of human rights, including the Nuremberg Code, the World Medical Association's Declaration of Helsinki, as revised (Helsinki IV) and the Belmont Report. These principles also underlie the Proposed International Guidelines for Biomedical Research Involving Human Subjects, issued by the Council for International Organizations of Medical Sciences in 1982. These and similar national codes are based on the model of clinical medicine, and often address interests of "patients" or individual "subjects".

Public health research concerns groups of people, and raises special issues. Ethical concerns often arise as a result of conflict among competing sets of values, such as, in the field of public health, the conflict between the rights of individuals and the needs of communities. Adherence to these guiding principles will not avoid all ethical problems in public health studies. Many situations require careful discussion and informed judgement on the part of investigators, ethical review committees, administrators, health-care practitioners, policy-makers, and community representatives

We believe that all public health research involving human subjects should be conducted in accordance with four basic ethical principles, namely: respect for persons, beneficence, the principle of 'do-no-harm', and justice.

Respect for persons incorporates two other fundamental ethical principles relevant to public health research, namely:

a) Autonomy, which requires that those who are capable of deliberation about their personal goals should be treated with respect for their capacity for self-determination and that their informed consent to participation will be sought. and

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<sup>1</sup> Based on two documents: *Guidelines for Defining Public Health Research and Public Health Non-Research*, Centers for Disease Control and Prevention, Atlanta, GA; and *International Guidelines for Ethical Review of Epidemiological Studies*, Council for International Organizations of Medical Sciences, Geneva, Switzerland.

b) Protection of persons with impaired or diminished autonomy, which requires that those who are dependent or vulnerable be afforded security against harm or abuse including that the informed consent of their legally authorized representative will be sought. Participants who are likely to be susceptible to undue influence or coercion may require additional safeguards in the study to protect them; and

Beneficence is the ethical principle that seeks to maximize possible benefits. This principle gives rise to norms requiring that the risks to participants in research are reasonable relative to the expected benefits, that the research design be sound, and that the investigators be competent both to conduct the research and to assure the well-being of the research subjects.

The principle of ‘Do- no- harm’ holds a central position in the tradition of medical ethics, and guards against avoidable harm to research subjects. It gives rise to norms requiring that the safety of participants in research is ensured, that the privacy of participants is adequately protected, that confidentiality of data is maintained, that the research design is sound and that participants are not exposed to unnecessary risks.

Justice requires that cases considered to be alike be treated alike, and that cases considered to be different be treated in ways that acknowledge the difference. When research involves dependent or vulnerable subjects, justice requires that the people studied come from the population that will receive benefit from the research.

The rules of justice apply within and among communities. Weaker members of communities should not bear disproportionate burdens of studies from which all members of the community are intended to benefit, and more dependent communities and countries should not bear disproportionate burdens of studies from which all communities or countries are intended to benefit.

We acknowledge that all ethical principles may not weigh equally. A study may be assessed as ethical even if a usual ethical expectation, such as confidentiality of data, has not been comprehensively met, provided the potential benefits clearly outweigh the risks and the investigators give assurances of minimizing risks. It may even be unethical to reject such a study, if its rejection would deny a community the benefits it offers. The challenge of ethical review is to make assessments that take into account potential risks and benefits, and to reach decisions on which members of our institutional review board may reasonably differ.

---Adopted unanimously by the Board, May 4, 2000.

## References

- “The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research”. April 18, 1979. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. U. S. Government Printing Office, Washington, D.C.
- “Ethical Principles for Medical Research Involving Human Subjects”. Adopted by the 18th World Medical Association (WMA) General Assembly, Helsinki, Finland, June 1964, and amended by the 29th WMA General Assembly, Tokyo, Japan, October 1975; 35th WMA General Assembly, Venice, Italy, October 1983; 41st WMA General Assembly, Hong Kong, September 1989; 48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996; and the 52nd WMA General Assembly, Edinburgh, Scotland, October 2000.
- “Protection of Human Subjects: Title 45, Code of Federal Regulations, Part 46. Revised, June 18, 1991. Reprinted March 15, 1994.” U.S. Government Printing Office, Washington, D.C.
- "Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10"*, Vol. 2, pp. 181-182. Washington, D.C.: U.S. Government Printing Office, 1949