# Virtual Mentor
American Medical Association Journal of Ethics
February 2011, Volume 13, Number 2: 100-101.

**THE CODE SAYS**
**The AMA *Code of Medical Ethics*' Opinion on Population-Based Genomic Research**

**Opinion 2.079 - Safeguards in the Use of DNA Databanks in Genomic Research**

The following safeguards should be applied to the use of databases for the purpose of population-based genomic research:

(1) Physicians who participate as investigators in genomic research should have adequate training in genomic research and related ethical issues so as to be able to discuss these issues with patients and/or potential research subjects.

(2) If research is to be conducted within a defined subset of the general population, that is, an identifiable community, then investigators should consult with the community to design a study that will minimize harm not only for individual subjects, but also for the community. When substantial opposition to the research is expressed within the community, investigators should not conduct the study. When the community supports a proposal, investigators nevertheless should obtain individual consent in the usual manner. The same procedure should be followed whether the investigators intend to collect new samples and data or whether they wish to use previously archived data sets.

(3) When obtaining the informed consent of individuals to participate in genomic research, standard informed consent requirements apply (see Opinion 2.07, "Clinical Investigation"). In addition:

(a) Special emphasis should be placed on disclosing the specific standards of privacy contained in the study: whether the material will be coded (i.e.: encrypted so that only the investigator can trace materials back to specific individuals) or be completely de-identified (i.e., stripped of identifiers).

(b) If data are to be coded, subjects should be told whether they can expect to be contacted in the future to share in findings or to consider participating in additional research, which may relate to the current protocol or extend to other research purposes.

(c) Individuals should always be free to refuse the use of their biological materials in research, without penalty.

(d) Disclosure should include information about whether investigators or subjects stand to gain financially from research findings (see Opinion 2.08, "Commercial Use of Human Tissue"). Such disclosure should refer to the possible conflicts of interest of the investigators (see Opinion 8.0315, "Managing Conflicts of Interest in the Conduct of Clinical Trials").

(e) Subjects should be informed of when, if ever, and how archived information and samples will be discarded.

(4) To strengthen the protection of confidentiality, genomic research should not be conducted using information and samples that identify the individuals from whom they were obtained (i.e., by name or social security number). Furthermore, to protect subsets of the population from such harms as stigmatization and discrimination, demographic information not required for the study's purposes should be coded.

Issued June 2002 based on the report "The Use of DNA Databanks in Genomic Research: The Imperative of Informed Consent," adopted December 2001.

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