



Preventing genetic discrimination

Relevant policies in the *AMA Code of Medical Ethics*

E-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 (ie: encrypted so that only the investigator can trace materials back to specific individuals) or be completely de-identified (ie: 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 (ie: 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. (I, IV, V, VII)

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E-2.132 Genetic Testing by Employers

As a result of the human genome project, physicians will be able to identify a greater number of genetic risks of disease. Among the potential uses of the tests that detect these risks will be screening of potential workers by employers. Employers may want to exclude workers with certain genetic risks from the workplace because these workers may become disabled prematurely, impose higher health care costs, or pose a risk to public safety. In addition, exposure to certain substances in the workplace may increase the likelihood that a disease will develop in the worker with a genetic risk for the disease.

(1) It would generally be inappropriate to exclude workers with genetic risks of disease from the workplace because of their risk. Genetic tests alone do not have sufficient predictive value to be relied upon as a basis for excluding workers. Consequently, use of the tests would result in unfair discrimination against individuals who have positive test results. In addition, there are other ways for employers to serve their legitimate interests. Tests of a worker's actual capacity to meet the demands of the job can be used to ensure future employability and protect the public's safety. Routine monitoring of a worker's exposure can be used to protect workers who have a genetic susceptibility to injury from a substance in the workplace. In addition, employees should be advised of the risks of injury to which they are being exposed.

(2) There may be a role for genetic testing in the exclusion from the workplace of workers who have a genetic susceptibility to injury. At a minimum, several conditions would have to be met:

- (a) The disease develops so rapidly that serious and irreversible injury would occur before monitoring of either the worker's exposure to the toxic substance or the worker's health status could be effective in preventing the harm.
- (b) The genetic testing is highly accurate, with sufficient sensitivity and specificity to minimize the risk of false negative and false positive test results.
- (c) Empirical data demonstrate that the genetic abnormality results in an unusually elevated susceptibility to occupational injury.
- (d) It would require undue cost to protect susceptible employees by lowering the level of the toxic substance in the workplace. The costs of lowering the level of the substance must be extraordinary relative to the employer's other costs of making the product for which the toxic substance is used. Since genetic testing with exclusion of susceptible employees is the alternative to cleaning up the workplace, the cost of lowering the level of the substance must also be extraordinary relative to the costs of using genetic testing.
- (e) Testing must not be performed without the informed consent of the employee or applicant for employment. (IV)

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E-2.135 Insurance Companies and Genetic Information

Physicians should not participate in genetic testing by health insurance companies to predict a person's predisposition for disease. As a corollary, it may be necessary for physicians to maintain separate files for genetic testing results to ensure that the results are not sent to health insurance companies when requests for copies of patient medical records are fulfilled. Physicians who withhold testing results should inform insurance companies that, when medical records are sent, genetic testing results are not included. This disclosure should occur with all patients, not just those who have undergone genetic testing. (IV)

Issued June 1994 based on the report "Physician Participation in Genetic Testing by Health Insurance Companies," adopted June 1993; Updated June 1996.