

AMA Code of Medical Ethics

7.3.7 Safeguards in the Use of DNA Databanks

DNA databanks facilitate population-based research into the genetic components of complex diseases. These databanks derive their power from integrating genetic and clinical data, as well as data on health, lifestyle, and environment about large samples of individuals. However, the use of DNA databanks in genomic research also raises the possibility of harm to individual participants, their families, and even populations.

Breach of confidentiality of information contained in DNA databanks may result in discrimination or stigmatization and may carry implications for important personal choices, such as reproductive choices. Human participants who contribute to research involving DNA databanks have a right to be informed about the nature and scope of the research and to make decisions about how their information may be used.

In addition to having adequate training to be able to discuss genomic research and related ethical issues with patients or prospective research participants, physician-researchers who are involved in genomic research using DNA databanks should:

Research involving individuals

- (a) Obtain informed consent from participants in genomic research, in keeping with ethics guidance. In addition, physicians should put special emphasis in the consent process on disclosing:
 - (i) the specific privacy standards to which the study will adhere, including whether the information or biological sample will be encrypted and remain identifiable to the researcher or will be completely de-identified;
 - (ii) whether participants whose data will be encrypted rather than de-identified can expect to be contacted in the future about findings or be invited to participate in additional research, either related to the current protocol or for other research purposes;
 - (iii) whether researchers or participants stand to gain financially from research findings, and any conflicts of interest researchers may have in regard to the research, in keeping with ethics guidance;
 - (iv) when, if ever, archived information or samples will be discarded;
 - (v) participants' freedom to refuse use of their biological materials without penalty.

Research involving identifiable communities

- (b) When research is to be conducted within a defined subset of the general population, physicians should:
 - (i) consult with the community in advance to design a study that is sensitive to community concerns and that will minimize harm for the community, as well as for individual participants. Physicians should not carry out a study when there is substantial opposition to the research within the community of interest;

- (ii) protect confidentiality by encrypting any demographic or identifying information that is not required for the study's purpose.

AMA Principles of Medical Ethics: I,IV,V,VI