

AMA Code of Medical Ethics

7.3.9 Commercial Use of Human Biological Materials

Research using human tissues has resulted in numerous commercially available products for use in both research and treatment. The development of these products raises questions about who holds property rights in human biological materials, how to distribute profits derived from human tissues equitably, and what constitutes appropriately informed consent when patients donate biological materials to research that may ultimately result in one or more commercial products.

Physicians involved in research with human biological materials should:

- (a) Disclose potential commercial applications to the tissue donor before a profit is realized on products developed from biological materials.
- (b) Obtain informed consent to use biological materials in research from the tissue donor. Human biological materials and their products may not be used for commercial purposes without the consent of the tissue donor.
- (c) Share profits from the commercial use of human biological materials with the tissue donor in accordance with lawful contractual agreements.

Physicians must make diagnostic and treatment recommendations in keeping with standards of good medical practice. They must not allow the commercial potential of the patient's tissue to influence professional judgment.

AMA Principles of Medical Ethics: II,V